

US3722025 (Prod: Keystone VitaLink Research - Greenville - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:25:29

All time stamps listed in this document are displayed in GMT

US3722025

Form: Participant Creation

Data signed: (b) (4) 28 Apr 2021 21:47:39

Generated On: 12 Aug 2021 13:25:29

Participant ID

US3722025

[mRNA-1273-P301 Completion Guidelines](#)

US3722025

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	02 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3722025

Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3722025

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Date of Informed Consent (*dd MMM yyyy*) 2 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1 ☒

Amendment 2 ☐

Amendment 3 ☐

Amendment 4 ☐

Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail

Withdrew Consent ☐

Inclusion/Exclusion ☐

Cohort Full ☐

Other ☐

If reason for screen fail is Other, specify _____

Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____

Enrollment Trigger 1

US3722025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3722025

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Were any significant conditions reported?

Yes ☒

No ☐

US3722025

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

US3722025

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 AUG 2020
Time of assessment (00:00-23:59)	07:55 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 07:55
Height (xxx.x)	(b) (6) cm
Weight (xxx.x)	142.2 lb
BMI (xxx.x)	(b) (6) kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722025

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3722025

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 09 Mar 2021 11:13:24

Generated On: 12 Aug 2021 13:25:29

Date of assessment (dd MMM yyyy) 2 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3722025

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 09 Mar 2021 11:13:25

Generated On: 12 Aug 2021 13:25:29

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 2 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3722025

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3722025

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

US3722025

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

What was the date of randomization? (dd MMM yyyy) 02 AUG 2020

What was the participant's randomization number? 142615

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☒ No ☐

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Height	ND - Not Done
Weight	ND - Not Done

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 AUG 2020
Time of assessment (00:00-23:59)	07:53 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 07:53
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 AUG 2020
Time of assessment (00:00-23:59)	09:04 (24 HR)
Vital Signs Date and Time (derived)	2 AUG 2020 09:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	94 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3722025

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 2 AUG 2020

What was the treatment time? (00:00-23:59) 08:34 (24 HR)

Treatment Date and Time (derived) 2 AUG 2020 08:34

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3722025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 AUG 2020
Collection time (00:00-23:59)	08:11 (24 HR)
Collection date and time (derived)	2 AUG 2020 08:11

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Collection date (dd MMM yyyy)			2 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:05	2 AUG 2020 08:05
Nasopharyngeal Swab 2	Yes	08:05	2 AUG 2020 08:05

US3722025

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐
No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp 02 AUG 2020 09:05

PC Open Date & Time 02 AUG 2020 08:54

PC Close Date & Time 02 AUG 2020 11:24

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	02 AUG 2020 17:17
PC Open Date & Time	02 AUG 2020 12:19
PC Close Date & Time	03 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.5 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	03 AUG 2020 20:05
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	04 AUG 2020 17:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

05 AUG 2020 21:11

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

06 AUG 2020 19:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

07 AUG 2020 22:40

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

09 AUG 2020 07:56

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 09:06

PC Open Date & Time

02 AUG 2020 08:54

PC Close Date & Time

02 AUG 2020 11:24

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 17:17

PC Open Date & Time

02 AUG 2020 12:19

PC Close Date & Time

03 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 19:56

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 AUG 2020 17:12

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 21:09

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 19:05

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 22:37

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 07:56

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 09:07
PC Open Date & Time	02 AUG 2020 08:54
PC Close Date & Time	02 AUG 2020 11:24

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	02 AUG 2020 17:18
PC Open Date & Time	02 AUG 2020 12:19
PC Close Date & Time	03 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

45 of 1693

EAB) (1725)

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 19:56
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

47 of 1693

EAB) (1725)

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 17:12
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

49 of 1693

EAB) (1725)

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:09
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:06
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

53 of 1693

EAB) (1725)

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 22:37
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

55 of 1693

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 07:55
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:54

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:55

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 10 AUG 2020 22:57

PC Open Date & Time 10 AUG 2020 12:00

PC Close Date & Time 11 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 11 AUG 2020 23:59

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	09 AUG 2020 19:55
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	10 AUG 2020 22:57
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 AUG 2020 23:59
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3722025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	15:19 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 15:19
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	16:38 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 16:38
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3722025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	28 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 16:08 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 16:08

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3722025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

15:41 (24 HR)

Collection date and time (derived)

28 AUG 2020 15:41

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:37	28 AUG 2020 15:37
Nasopharyngeal Swab 2	Yes	15:37	28 AUG 2020 15:37

US3722025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐
No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp 28 AUG 2020 16:35

PC Open Date & Time 28 AUG 2020 16:28

PC Close Date & Time 28 AUG 2020 18:58

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp	29 AUG 2020 08:17
PC Open Date & Time	28 AUG 2020 19:53
PC Close Date & Time	29 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	95.8 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	29 AUG 2020 22:53
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

30 AUG 2020 20:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

31 AUG 2020 23:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

01 SEP 2020 23:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

02 SEP 2020 18:28

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

03 SEP 2020 22:42

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 16:36

PC Open Date & Time

28 AUG 2020 16:28

PC Close Date & Time

28 AUG 2020 18:58

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 08:19

PC Open Date & Time

28 AUG 2020 19:53

PC Close Date & Time

29 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 20:21

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 20:15

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 23:13

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 22:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 18:27

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 22:42

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 16:37
PC Open Date & Time	28 AUG 2020 16:28
PC Close Date & Time	28 AUG 2020 18:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 08:18
PC Open Date & Time	28 AUG 2020 19:53
PC Close Date & Time	29 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 20:21
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:15
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:14
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

105 of 1693

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:27
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 22:42
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3722025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	15:48 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 15:48
Temperature (xxx.x)	98 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3722025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

15:56 (24 HR)

Collection date and time (derived)

29 SEP 2020 15:56

US3722025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 13:53:44

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 OCT 2020 16:04:46
Patient Cloud Open Date & Time	02 OCT 2020 00:01
Patient Cloud Close Date & Time	06 OCT 2020 23:59

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

11 OCT 2020 17:12:48

Patient Cloud Open Date & Time

09 OCT 2020 00:01

Patient Cloud Close Date & Time

13 OCT 2020 23:59

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 OCT 2020 00:01:30

Patient Cloud Open Date & Time

16 OCT 2020 00:01

Patient Cloud Close Date & Time

20 OCT 2020 23:59

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 17:44:21
Patient Cloud Open Date & Time	30 OCT 2020 00:01
Patient Cloud Close Date & Time	03 NOV 2020 23:59

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 99

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 NOV 2020 12:03:24

Patient Cloud Open Date & Time

06 NOV 2020 00:01

Patient Cloud Close Date & Time

10 NOV 2020 23:59

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 106

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

13 NOV 2020 08:00:24

Patient Cloud Open Date & Time

13 NOV 2020 00:01

Patient Cloud Close Date & Time

17 NOV 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

26 NOV 2020 18:54:05

Patient Cloud Open Date & Time

24 NOV 2020 00:01

Patient Cloud Close Date & Time

28 NOV 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 124

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

01 DEC 2020 00:13:26

Patient Cloud Open Date & Time

01 DEC 2020 00:01

Patient Cloud Close Date & Time

05 DEC 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 DEC 2020 12:35:49

Patient Cloud Open Date & Time

08 DEC 2020 00:01

Patient Cloud Close Date & Time

12 DEC 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

15 DEC 2020 13:19:32

Patient Cloud Open Date & Time

15 DEC 2020 00:01

Patient Cloud Close Date & Time

19 DEC 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

22 DEC 2020 17:38:36

Patient Cloud Open Date & Time

22 DEC 2020 00:01

Patient Cloud Close Date & Time

26 DEC 2020 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

30 DEC 2020 23:39:57

Patient Cloud Open Date & Time

29 DEC 2020 00:01

Patient Cloud Close Date & Time

02 JAN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 13:53:27
Patient Cloud Open Date & Time	05 JAN 2021 00:01
Patient Cloud Close Date & Time	09 JAN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

12 JAN 2021 07:08:01

Patient Cloud Open Date & Time

12 JAN 2021 00:01

Patient Cloud Close Date & Time

16 JAN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

19 JAN 2021 19:08:11

Patient Cloud Open Date & Time

19 JAN 2021 00:01

Patient Cloud Close Date & Time

23 JAN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 01:18:17
Patient Cloud Open Date & Time	26 JAN 2021 00:01
Patient Cloud Close Date & Time	30 JAN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 07:30:01
Patient Cloud Open Date & Time	02 FEB 2021 00:01
Patient Cloud Close Date & Time	06 FEB 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 FEB 2021 08:02:58
Patient Cloud Open Date & Time	09 FEB 2021 00:01
Patient Cloud Close Date & Time	13 FEB 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

18 FEB 2021 12:00:52

Patient Cloud Open Date & Time

16 FEB 2021 00:01

Patient Cloud Close Date & Time

20 FEB 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 FEB 2021 04:12:37

Patient Cloud Open Date & Time

23 FEB 2021 00:01

Patient Cloud Close Date & Time

27 FEB 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 MAR 2021 12:28:28

Patient Cloud Open Date & Time

02 MAR 2021 00:01

Patient Cloud Close Date & Time

06 MAR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

09 MAR 2021 07:47:54

Patient Cloud Open Date & Time

09 MAR 2021 00:01

Patient Cloud Close Date & Time

13 MAR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 12:47:09
Patient Cloud Open Date & Time	16 MAR 2021 00:01
Patient Cloud Close Date & Time	20 MAR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 MAR 2021 15:51:29
Patient Cloud Open Date & Time	23 MAR 2021 00:01
Patient Cloud Close Date & Time	27 MAR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

31 MAR 2021 12:32:51

Patient Cloud Open Date & Time

30 MAR 2021 00:01

Patient Cloud Close Date & Time

03 APR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

06 APR 2021 16:55:45

Patient Cloud Open Date & Time

06 APR 2021 00:01

Patient Cloud Close Date & Time

10 APR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

13 APR 2021 08:09:26

Patient Cloud Open Date & Time

13 APR 2021 00:01

Patient Cloud Close Date & Time

17 APR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

23 APR 2021 14:10:42

Patient Cloud Open Date & Time

20 APR 2021 00:01

Patient Cloud Close Date & Time

24 APR 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 271

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

27 APR 2021 07:56:08

Patient Cloud Open Date & Time

27 APR 2021 00:01

Patient Cloud Close Date & Time

01 MAY 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2021 00:01
Patient Cloud Close Date & Time	17 JUL 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2021 00:01
Patient Cloud Close Date & Time	31 JUL 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	10 AUG 2021 00:01
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Patient Cloud Close Date & Time	14 AUG 2021 23:59
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US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2021 00:01
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Patient Cloud Close Date & Time	09 OCT 2021 23:59
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US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 446

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2021 00:01
Patient Cloud Close Date & Time	30 OCT 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

20 NOV 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 495

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

11 DEC 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2021 00:01
Patient Cloud Close Date & Time	18 DEC 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2021 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

28 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JAN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JAN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JAN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JAN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JAN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

05 FEB 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

12 FEB 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

19 FEB 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 FEB 2022 00:01
Patient Cloud Close Date & Time	26 FEB 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 APR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 APR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 APR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 APR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 APR 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAY 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 649

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAY 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAY 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	28 JUN 2022 00:01
Patient Cloud Close Date & Time	02 JUL 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUL 2022 00:01
Patient Cloud Close Date & Time	30 JUL 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

06 AUG 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

27 AUG 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

30 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

03 SEP 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2022 00:01
Patient Cloud Close Date & Time	10 SEP 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2022 00:01
Patient Cloud Close Date & Time	17 SEP 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

24 SEP 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2022 23:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

04 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

08 OCT 2022 23:59

US3722025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:25:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	03 MAR 2021 12:28:44

US3722025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 17:12:14

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 17:12:14

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 JAN 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

If Contact Not Made, please provide Comments

SEVERAL ATTEMPTS HAVE
BEEN MADE TO CONTACT
SUBJECT FOR SITE CALL VISIT
BUT HAVE NOT BEEN
SUCCESSFUL WITH REACHING
PATIENT OR RECEIVED A CALL
BACK. VISIT HAS NOW BEEN
CLOSED.

US3722025

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	10 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 FEB 2021
Time of assessment (00:00-23:59)	08:21 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 08:21
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3722025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 FEB 2021

Collection time (00:00-23:59)

08:29 (24 HR)

Collection date and time (derived)

10 FEB 2021 08:29

US3722025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 11:13:29

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3722025

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3722025

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3722025

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:25:29

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3722025

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:25:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	8 JAN 2021
--------------------------	------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Date of updated informed consent (dd MMM yyyy) 8 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 8 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 JAN 2021
Collection time (00:00-23:59)	16:18 (24 HR)
Collection date and time (derived)	8 JAN 2021 16:18

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	8 JAN 2021
-------------------------------	------------

Collection time (00:00 - 23:59)	16:19
---------------------------------	-------

Collection Date and Time (derived)	8 JAN 2021 16:19
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US3722025

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:47:40

Generated On: 12 Aug 2021 13:25:29

AEID

Adverse event

FATIGUE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☒

No ☐

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

2 AUG 2020

Start time (00:00-23:59)

13:00 (24 HR)

AE start date and time (derived)

2 AUG 2020 13:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 AUG 2020

End time (00:00-23:59)

20:00 (24 HR)

AE End Date and Time (derived)

10 AUG 2020 20:00

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

330 of 1693

EAB) (1725)

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 21:47:40

Generated On: 12 Aug 2021 13:25:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

333 of 1693

EAB) (1725)

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	3 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Name of Medication LOESTRIN FE

Prophylaxis Yes ☐
No ☒

Indication BIRTH CONTROL

Dose per administration 1/20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 1693

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2007
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3722025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Apr 2021 21:47:41

Generated On: 12 Aug 2021 13:25:29

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3722025

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:25:29

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3722025

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:25:29

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3722025 (Prod: Keystone VitaLink Research - Greenville - PPDS)

US3722025

Form: Participant Creation

Generated On: 12 Aug 2021 13:25:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:39
User entered 'US3722025'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 11:29:07

US3722025

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Aug 2020 12:37:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Aug 2020 12:37:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Ford (b) (4)	02 Aug 2020 12:37:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Aug 2020 12:37:25
User entered empty.	System	02 Aug 2020 12:37:25
	Amy Ford (b) (4)	02 Aug 2020 12:37:25
	(b) (4)	

US3722025

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '02 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 11:29:08

US3722025

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	02 Aug 2020 12:37:25

US3722025

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'SCRN'	System	02 Aug 2020 12:37:31
User entered empty.	System	02 Aug 2020 12:37:25

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 11:29:08

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '30'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'YEARS'	System	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered '30'	System	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Female (F)'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User closed query 'Race has not been provided. Please correct.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	02 Aug 2020 12:38:05
User opened query 'Race has not been provided. Please correct.' (Site from System).	Amy Ford (b) (4)	02 Aug 2020 12:38:05
User entered '0'	(b) (4)	
	System	02 Aug 2020 12:37:51
	Amy Ford (b) (4)	02 Aug 2020 12:37:51
	(b) (4)	

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:25:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:37:51

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '2 Aug 2020'	Amy Ford (b) (4)	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'Aug 2020'	System	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered '2020'	System	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User closed query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Sep 2020 19:51:15
Query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' answered with 'completed' (Site from DM).	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:27:49
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	17 Sep 2020 14:27:45
User opened query 'Per CDM: Protocol Version is recorded as Amendment 5, however to date there is no Amendment 5, please review and update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 06:52:10
User entered 'Amendment 5 (5)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:38:32

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 11:29:08

US3722025

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:25:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'I'	System	02 Aug 2020 12:38:51

US3722025

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:25:29

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 12:38:51

US3722025

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:25:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:36:07

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:38:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 15:38:06
Data point term sent to Coder	System	05 Aug 2020 15:37:18
User entered 'Deviated septum'	Kayla Peay (b) (4)	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'UN UNK 2000'	Kayla Peay (b) (4)	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Kayla Peay (b) (4)	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Kayla Peay (b) (4)	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'Jan 2000'	System	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered '2000'	System	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered empty.	System	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:25:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered empty.	System	05 Aug 2020 15:36:40

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '07:55'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered '2 Aug 2020 07:55'	System	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User closed query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 06:00:33
Query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' answered with 'height is correct' (Site from System).	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 15:36:08
User entered (b) (6) ' cm reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	18 Sep 2020 15:35:47
Amendment Manager: User opened query 'Height reported is out of range <= 121.92cm (48in) OR >= 228.6cm (90in). Please reconcile.' (Site from System).	System	16 Sep 2020 23:40:39
User closed query 'Per CDM: please recheck Height and Weight and update accordingly.' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 13:15:50
Query 'Per CDM: please recheck Height and Weight and update accordingly.' answered with 'data is correct' (Site from DM).	Kayla Peay (b) (4) (b) (4)	27 Aug 2020 18:08:45
User opened query 'Per CDM: please recheck Height and Weight and update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:47:05
User entered (b) (6) ' in reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	07 Aug 2020 15:57:44
User entered (b) (6) ' cm	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:38:11
DataPoint set to visible.	System	02 Aug 2020 12:38:51

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '142.2' lb reason for change: Data Entry Error	(b) (4)	07 Aug 2020 15:57:44
User entered '64.5' kg	Kayla Peay (b) (4)	05 Aug 2020 15:38:11
DataPoint set to visible.	(b) (4) System	02 Aug 2020 12:38:51

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered (b) (6) '	System	18 Sep 2020 15:35:47
Amendment Manager: User entered (b) (6) '	System	16 Sep 2020 23:40:39
User entered (b) (6) '	System	07 Aug 2020 15:57:44
User entered (b) (6) '	System	05 Aug 2020 15:38:11
DataPoint set to visible.	System	02 Aug 2020 12:38:51

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'kg/m2'	System	05 Aug 2020 15:38:11
DataPoint set to visible.	System	02 Aug 2020 12:38:51

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:33:19
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'data corrected' (Site from DM).	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:06
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:46:06
User entered '97.8' F	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered empty; reason for change Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	08 Sep 2020 12:37:06
User entered 'Oral (Oral)'	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:38:11
	(b) (4)	

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 12:37:06
User entered '78'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11
	(b) (4)	

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'bpm'	System	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 12:37:06
User entered '17'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11
	(b) (4)	

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'breaths/min'	System	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 12:37:06
User entered '103'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11
	(b) (4)	

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'mmHg'	System	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	08 Sep 2020 12:37:06
User entered '72'	Kayla Peay (b) (4)	05 Aug 2020 15:38:11
	(b) (4)	

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered 'mmHg'	System	05 Aug 2020 15:38:11

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40

US3722025

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40

US3722025

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:38:32

US3722025

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 14:06:32
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Aug 2020 20:25:05
User entered '2 Aug 2020'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:38:32

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:25:29

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '0'	Kayla Peay (b) (4)	05 Aug 2020 15:38:50

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:25
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User entered empty.	System	05 Aug 2020 15:39:15

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Aug 2020 15:39:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 15:39:29
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4)	05 Aug 2020 15:39:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Aug 2020 12:40:05
User entered empty.	System	02 Aug 2020 12:40:05
	Amy Ford (b) (4)	02 Aug 2020 12:40:05
	(b) (4)	

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered 'I'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered '0'	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:25:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:02:40
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:40:05

US3722025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 12:40:34

US3722025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '2 Aug 2020'	Amy Ford (b) (4)	02 Aug 2020 12:40:34

US3722025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Clinic (Clinic)'	Amy Ford (b) (4)	02 Aug 2020 12:40:34

US3722025

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'VISIT1'	System	02 Aug 2020 12:40:34

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '02 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 12:14:06

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:39:43
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:39:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	02 Aug 2020 12:14:06
User entered '142615' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 12:14:06

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	
	System	04 Aug 2020 12:29:12
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	02 Aug 2020 12:41:03
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Aug 2020 12:14:06

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:41:03

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:41:03

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Jan 2021 20:19:36
Query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly. ' answered with 'Subject has not been diagnosed with Severe Obesity. ' (Site from DM).	Marlee Smith (b) (4) (b) (4)	11 Jan 2021 19:21:47
User opened query 'Per CDM: Please note Severe Obesity is recorded as "Yes", however corresponding entry has not been made in Medical History Page. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 19:40:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	04 Aug 2020 12:29:12
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	02 Aug 2020 12:41:03

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:41:03

US3722025

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:25:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'No (N)'	Amy Ford (b) (4)	02 Aug 2020 12:41:03

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:32:39
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'data corrected' (Site from DM).	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:46
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:47:45
User entered (b) (6) in reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	08 Sep 2020 12:37:46
User entered '142.2' lb reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:32:39
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'data corrected' (Site from DM).	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:46
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:47:45
User entered (b) (6) ' in reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	08 Sep 2020 12:37:46
User entered '142.2' lb reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '2 Aug 2020' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '07:53' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '2 Aug 2020 07:53'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '97.8' F reason for change: Data Entry Error	(b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '78' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'bpm'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '17' reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4) Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'breaths/min'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '103' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'mmHg'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '72' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'mmHg'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:32:39
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'data corrected' (Site from DM).	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:46
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:47:45
User entered (b) (6) ' in reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:25:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Kayla Peay (b) (4)	08 Sep 2020 12:37:46
User entered '142.2' lb reason for change: Data Entry Error	(b) (4) Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '2 Aug 2020' reason for change: Data Entry Error	(b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 04:51:37
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct per protocol' (Site from System).	Amy Ford (b) (4) (b) (4)	17 Aug 2020 17:36:43
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		11 Aug 2020 13:04:50
User entered '09:04' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '2 Aug 2020 09:04'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '98.4' F reason for change: Data Entry Error	(b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '67' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'bpm'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'breaths/min'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '94' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'mmHg'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '69' reason for change: Data Entry Error	(b) (4)	
	Kayla Peay (b) (4)	11 Aug 2020 13:04:50
User entered empty.	(b) (4)	
	Kayla Peay (b) (4)	05 Aug 2020 15:39:45
	(b) (4)	

US3722025

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'mmHg'	System	11 Aug 2020 13:04:50
User entered empty.	System	05 Aug 2020 15:39:45

US3722025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:32:45
Query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date.' answered with 'data corrected' (Site from DM).	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:36
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	08 Sep 2020 12:37:30
User opened query 'Per CDM: per pages 15-16 of the CCGs, please record this as NO and remove date.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:48:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:02:09
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:51

US3722025

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	08 Sep 2020 12:37:30
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:02:09
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:51

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM: Please record this as NO and remove data except FSH.' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Sep 2020 12:55:04
Query 'Per CDM: Please record this as NO and remove data except FSH.' answered with 'updated' (Site from DM).	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:30:39
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:30:31
User opened query 'Per CDM: Please record this as NO and remove data except FSH.' (Site from DM).	(b) (4), (b) (6)	22 Aug 2020 20:48:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:02:42
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 18:30:31
User entered '2 Aug 2020' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:02:42
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 18:30:31
User entered 'Urine (URINE)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:02:42
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4)	11 Sep 2020 18:30:31
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	Kayla Peay (b) (4)	11 Aug 2020 13:02:42
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Per CDM : Please enter Yes/No in "Was FSH sample collected". ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 16:33:54
Query 'Per CDM : Please enter Yes/No in "Was FSH sample collected". ' answered with 'updated' (Site from DM).	Kayla Peay (b) (4) (b) (4)	15 Sep 2020 13:59:56
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	15 Sep 2020 13:59:49
User opened query 'Per CDM : Please enter Yes/No in "Was FSH sample collected". ' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 12:55:02
User entered empty; reason for change Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Sep 2020 18:30:31
User entered 'No (N)' reason for change: Data Entry Error	Kayla Peay (b) (4) (b) (4)	11 Aug 2020 13:02:42
User entered empty.	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered empty.	System	05 Aug 2020 15:39:55

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Amy Ford (b) (4)	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'MRNA-1273 OR PLACEBO'	System	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '2 Aug 2020'	Amy Ford (b) (4)	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '08:34'	Amy Ford (b) (4)	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '2 Aug 2020 08:34'	System	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Left Arm (LEFT ARM)'	Amy Ford (b) (4)	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'ONCE'	System	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'INTRAMUSCULAR'	System	02 Aug 2020 12:41:54

US3722025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:40:29

US3722025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 15:40:29

US3722025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '08:11'	Kayla Peay (b) (4)	05 Aug 2020 15:40:29

US3722025

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '2 Aug 2020 08:11'	System	05 Aug 2020 15:40:29

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:25:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '2 Aug 2020'	Kayla Peay (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '08:05'	Kayla Peay (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '2 Aug 2020 08:05'	System	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '08:05'	Kayla Peay (b) (4)	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '2 Aug 2020 08:05'	System	05 Aug 2020 15:40:57

US3722025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	05 Aug 2020 15:41:01

US3722025

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'I'	System	05 Aug 2020 15:41:01

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:02', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ab6e593-bc87-447d-9762-0535e155bec1' User entered 'Yes (Y)'	System	02 Aug 2020 13:05:30
	System	02 Aug 2020 13:05:30

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ab6e593-bc87-447d-9762-0535e155bec1' User entered '98.4'	System	02 Aug 2020 13:05:30
	System	02 Aug 2020 13:05:30

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:14', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ab6e593-bc87-447d-9762-0535e155bec1' User entered 'No (N)'	System	02 Aug 2020 13:05:30
	System	02 Aug 2020 13:05:30

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:28', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ab6e593-bc87-447d-9762-0535e155bec1' User entered '02 Aug 2020 09:05'	System	02 Aug 2020 13:05:30
	System	02 Aug 2020 13:05:30

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 08:54'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 11:24'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:16:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dfc7dd84-b562-4ab3-b8e9-3c7bb1201f7d' User entered 'Yes (Y)'	System	02 Aug 2020 21:17:22
	System	02 Aug 2020 21:17:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:03', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dfc7dd84-b562-4ab3-b8e9-3c7bb1201f7d' User entered '98.4'	System	02 Aug 2020 21:17:22
	System	02 Aug 2020 21:17:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dfc7dd84-b562-4ab3-b8e9-3c7bb1201f7d'	System	02 Aug 2020 21:17:22
User entered 'No (N)'	System	02 Aug 2020 21:17:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dfc7dd84-b562-4ab3-b8e9-3c7bb1201f7d'	System	02 Aug 2020 21:17:22
User entered '02 Aug 2020 17:17'	System	02 Aug 2020 21:17:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 12:19'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 2'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T20:05:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a20d6f6c-a6c3-466f-a1de-8b61beda257c' User entered 'Yes (Y)'	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T20:05:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a20d6f6c-a6c3-466f-a1de-8b61beda257c' User entered '97.5'	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T20:05:27', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a20d6f6c-a6c3-466f-a1de-8b61beda257c' User entered 'Yes (Y)'	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRMED' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 09:11:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T20:05:31', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a20d6f6c-a6c3-466f-a1de-8b61beda257c' User entered '1'	Amy Ford (b) (4) (b) (4)	09 Aug 2020 18:27:38
	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T20:05:31', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a20d6f6c-a6c3-466f-a1de-8b61beda257c' User entered '0'	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T20:05:34', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a20d6f6c-a6c3-466f-a1de-8b61beda257c' User entered '03 Aug 2020 20:05'	System	04 Aug 2020 00:05:36
	System	04 Aug 2020 00:05:36

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 3'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:14:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '0e0c5ad5-a099-4dfc-8f66-0a4f324c9f6b' User entered 'Yes (Y)'	System	04 Aug 2020 21:15:39
	System	04 Aug 2020 21:15:39

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:15:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '0e0c5ad5-a099-4dfc-8f66-0a4f324c9f6b' User entered '98.0'	System	04 Aug 2020 21:15:39
	System	04 Aug 2020 21:15:39

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:15:20', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '0e0c5ad5-a099-4dfc-8f66-0a4f324c9f6b'	System	04 Aug 2020 21:15:39
User entered 'Yes (Y)'	System	04 Aug 2020 21:15:39

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRMED' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 09:11:59
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:15:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '0e0c5ad5-a099-4dfc-8f66-0a4f324c9f6b'	Amy Ford (b) (4) (b) (4)	09 Aug 2020 18:28:14
User entered '1'	System	04 Aug 2020 21:15:39

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:15:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '0e0c5ad5-a099-4dfc-8f66-0a4f324c9f6b' User entered '0'	System	04 Aug 2020 21:15:39
	System	04 Aug 2020 21:15:39

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:15:35', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '0e0c5ad5-a099-4dfc-8f66-0a4f324c9f6b' User entered '04 Aug 2020 17:15'	System	04 Aug 2020 21:15:39
	System	04 Aug 2020 21:15:39

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 4'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:11:09', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '916130a7-bb64-441d-9fc0-cab20e8fc754'	System	06 Aug 2020 01:11:28
User entered 'Yes (Y)'	System	06 Aug 2020 01:11:28

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:11:14', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '916130a7-bb64-441d-9fc0-cab20e8fc754' User entered '97.3'	System	06 Aug 2020 01:11:28
	System	06 Aug 2020 01:11:28

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:11:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '916130a7-bb64-441d-9fc0-cab20e8fc754'	System	06 Aug 2020 01:11:28
User entered 'Yes (Y)'	System	06 Aug 2020 01:11:28

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRMED' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 09:12:46
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Amy Ford (b) (4)	09 Aug 2020 18:28:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:11:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '916130a7-bb64-441d-9fc0-cab20e8fc754'	(b) (4)	
User entered '1'	System	06 Aug 2020 01:11:28
	System	06 Aug 2020 01:11:28
	System	06 Aug 2020 01:11:28

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:11:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '916130a7-bb64-441d-9fc0-cab20e8fc754'	System	06 Aug 2020 01:11:28
User entered '0'	System	06 Aug 2020 01:11:28

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:11:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '916130a7-bb64-441d-9fc0-cab20e8fc754'	System	06 Aug 2020 01:11:28
User entered '05 Aug 2020 21:11'	System	06 Aug 2020 01:11:28

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 5'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c9984582-d5a5-49c8-b0a6-237aafe7fe57'	System	06 Aug 2020 23:05:40
User entered 'Yes (Y)'	System	06 Aug 2020 23:05:40

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:27', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c9984582-d5a5-49c8-b0a6-237aafe7fe57'	System	06 Aug 2020 23:05:40
User entered '97.9'	System	06 Aug 2020 23:05:40

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:37', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c9984582-d5a5-49c8-b0a6-237aafe7fe57'	System	06 Aug 2020 23:05:40
User entered 'No (N)'	System	06 Aug 2020 23:05:40

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c9984582-d5a5-49c8-b0a6-237aafe7fe57'	System	06 Aug 2020 23:05:40
User entered '06 Aug 2020 19:05'	System	06 Aug 2020 23:05:40

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 6'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd27f0df5-283c-462f-b914-ad3a4c20d7de' User entered 'Yes (Y)'	System	08 Aug 2020 02:40:04
	System	08 Aug 2020 02:40:04

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:39:52', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd27f0df5-283c-462f-b914-ad3a4c20d7de' User entered '97.5'	System	08 Aug 2020 02:40:04
	System	08 Aug 2020 02:40:04

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:39:55', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd27f0df5-283c-462f-b914-ad3a4c20d7de'	System	08 Aug 2020 02:40:04
User entered 'Yes (Y)'	System	08 Aug 2020 02:40:04

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONFIRMED' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 09:13:06
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Amy Ford (b) (4)	09 Aug 2020 18:29:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:39:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd27f0df5-283c-462f-b914-ad3a4c20d7de'	(b) (4)	
User entered '1'	System	08 Aug 2020 02:40:04
	System	08 Aug 2020 02:40:04
	System	08 Aug 2020 02:40:04

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:39:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd27f0df5-283c-462f-b914-ad3a4c20d7de' User entered '0'	System	08 Aug 2020 02:40:04
	System	08 Aug 2020 02:40:04

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:40:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd27f0df5-283c-462f-b914-ad3a4c20d7de' User entered '07 Aug 2020 22:40'	System	08 Aug 2020 02:40:04
	System	08 Aug 2020 02:40:04

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 7'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:56:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '34ef32c2-55d4-47b6-8908-b515d22be159'	System	09 Aug 2020 11:56:22
User entered 'Yes (Y)'	System	09 Aug 2020 11:56:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:56:14', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '34ef32c2-55d4-47b6-8908-b515d22be159' User entered '97.5'	System	09 Aug 2020 11:56:22
	System	09 Aug 2020 11:56:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:56:18', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '34ef32c2-55d4-47b6-8908-b515d22be159'	System	09 Aug 2020 11:56:22
User entered 'No (N)'	System	09 Aug 2020 11:56:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:56:20', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '34ef32c2-55d4-47b6-8908-b515d22be159'	System	09 Aug 2020 11:56:22
User entered '09 Aug 2020 07:56'	System	09 Aug 2020 11:56:22

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f98d1796-2863-44d0-b7c5-2a501435370e'	System	02 Aug 2020 13:06:28
User entered 'None (1)'	System	02 Aug 2020 13:06:28

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:52', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f98d1796-2863-44d0-b7c5-2a501435370e' User entered 'No (N)'	System	02 Aug 2020 13:06:28
	System	02 Aug 2020 13:06:28

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:05:54', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f98d1796-2863-44d0-b7c5-2a501435370e' User entered 'No (N)'	System	02 Aug 2020 13:06:28
	System	02 Aug 2020 13:06:28

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:03', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f98d1796-2863-44d0-b7c5-2a501435370e'	System	02 Aug 2020 13:06:28
User entered 'None (1)'	System	02 Aug 2020 13:06:28

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:26', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f98d1796-2863-44d0-b7c5-2a501435370e' User entered '02 Aug 2020 09:06'	System	02 Aug 2020 13:06:28
	System	02 Aug 2020 13:06:28

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 08:54'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 11:24'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3dca0ca-d91e-4ba9-9358-970d6a04e98d'	System	02 Aug 2020 21:17:46
User entered 'Does not interfere with activity (2)'	System	02 Aug 2020 21:17:46

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:31', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3dca0ca-d91e-4ba9-9358-970d6a04e98d' User entered 'No (N)'	System	02 Aug 2020 21:17:46
	System	02 Aug 2020 21:17:46

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:35', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3dca0ca-d91e-4ba9-9358-970d6a04e98d' User entered 'No (N)'	System	02 Aug 2020 21:17:46
	System	02 Aug 2020 21:17:46

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3dca0ca-d91e-4ba9-9358-970d6a04e98d' User entered 'None (1)'	System	02 Aug 2020 21:17:46
	System	02 Aug 2020 21:17:46

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3dca0ca-d91e-4ba9-9358-970d6a04e98d' User entered '02 Aug 2020 17:17'	System	02 Aug 2020 21:17:46
	System	02 Aug 2020 21:17:46

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 12:19'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 2'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:33', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '17e07cc7-aaba-42b1-bf77-aa96f3aecca2'	System	03 Aug 2020 23:57:01
User entered 'Does not interfere with activity (2)'	System	03 Aug 2020 23:57:01

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:38', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '17e07cc7-aaba-42b1-bf77-aa96f3aecca2'	System	03 Aug 2020 23:57:01
User entered 'No (N)'	System	03 Aug 2020 23:57:01

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:45', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '17e07cc7-aaba-42b1-bf77-aa96f3aecca2'	System	03 Aug 2020 23:57:01
User entered 'No (N)'	System	03 Aug 2020 23:57:01

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:54', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '17e07cc7-aaba-42b1-bf77-aa96f3aecca2'	System	03 Aug 2020 23:57:01
User entered 'None (1)'	System	03 Aug 2020 23:57:01

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '17e07cc7-aaba-42b1-bf77-aa96f3aecca2' User entered '03 Aug 2020 19:56'	System	03 Aug 2020 23:57:01
	System	03 Aug 2020 23:57:01

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 3'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c3fc9136-bd8a-45e9-9644-a622f80ed311'	System	04 Aug 2020 21:12:52
User entered 'None (1)'	System	04 Aug 2020 21:12:52

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:38', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c3fc9136-bd8a-45e9-9644-a622f80ed311'	System	04 Aug 2020 21:12:52
User entered 'No (N)'	System	04 Aug 2020 21:12:52

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c3fc9136-bd8a-45e9-9644-a622f80ed311' User entered 'No (N)'	System	04 Aug 2020 21:12:52
	System	04 Aug 2020 21:12:52

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c3fc9136-bd8a-45e9-9644-a622f80ed311' User entered 'None (1)'	System	04 Aug 2020 21:12:52
	System	04 Aug 2020 21:12:52

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:50', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c3fc9136-bd8a-45e9-9644-a622f80ed311' User entered '04 Aug 2020 17:12'	System	04 Aug 2020 21:12:52
	System	04 Aug 2020 21:12:52

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 4'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c066408e-119a-4110-a150-0f0e41132510'	System	06 Aug 2020 01:09:50
User entered 'None (1)'	System	06 Aug 2020 01:09:50

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c066408e-119a-4110-a150-0f0e41132510'	System	06 Aug 2020 01:09:50
User entered 'No (N)'	System	06 Aug 2020 01:09:50

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c066408e-119a-4110-a150-0f0e41132510' User entered 'No (N)'	System	06 Aug 2020 01:09:50
	System	06 Aug 2020 01:09:50

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:46', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c066408e-119a-4110-a150-0f0e41132510' User entered 'None (1)'	System	06 Aug 2020 01:09:50
	System	06 Aug 2020 01:09:50

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c066408e-119a-4110-a150-0f0e41132510' User entered '05 Aug 2020 21:09'	System	06 Aug 2020 01:09:50
	System	06 Aug 2020 01:09:50

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 5'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '70005496-db05-4065-83d6-ad9dcbdac859'	System	06 Aug 2020 23:05:57
User entered 'None (1)'	System	06 Aug 2020 23:05:57

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:45', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '70005496-db05-4065-83d6-ad9dcbdac859'	System	06 Aug 2020 23:05:57
User entered 'No (N)'	System	06 Aug 2020 23:05:57

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '70005496-db05-4065-83d6-ad9dcbdac859'	System	06 Aug 2020 23:05:57
User entered 'No (N)'	System	06 Aug 2020 23:05:57

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:49', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '70005496-db05-4065-83d6-ad9dcbdac859'	System	06 Aug 2020 23:05:57
User entered 'None (1)'	System	06 Aug 2020 23:05:57

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:05:54', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '70005496-db05-4065-83d6-ad9dcbdac859'	System	06 Aug 2020 23:05:57
User entered '06 Aug 2020 19:05'	System	06 Aug 2020 23:05:57

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 6'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '7b18dad8-5fa6-4b6f-b70f-5bf66001f0c5'	System	08 Aug 2020 02:37:41
User entered 'None (1)'	System	08 Aug 2020 02:37:41

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '7b18dad8-5fa6-4b6f-b70f-5bf66001f0c5' User entered 'No (N)'	System	08 Aug 2020 02:37:41
	System	08 Aug 2020 02:37:41

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '7b18dad8-5fa6-4b6f-b70f-5bf66001f0c5' User entered 'No (N)'	System	08 Aug 2020 02:37:41
	System	08 Aug 2020 02:37:41

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '7b18dad8-5fa6-4b6f-b70f-5bf66001f0c5'	System	08 Aug 2020 02:37:41
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 02:37:41

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:38', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '7b18dad8-5fa6-4b6f-b70f-5bf66001f0c5' User entered '07 Aug 2020 22:37'	System	08 Aug 2020 02:37:41
	System	08 Aug 2020 02:37:41

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 7'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:55', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '16bebd17-9fa5-49ff-8274-0b0005e4cfe0'	System	09 Aug 2020 11:56:06
User entered 'None (1)'	System	09 Aug 2020 11:56:06

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '16bebd17-9fa5-49ff-8274-0b0005e4cfe0' User entered 'No (N)'	System	09 Aug 2020 11:56:06
	System	09 Aug 2020 11:56:06

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:59', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '16bebd17-9fa5-49ff-8274-0b0005e4cfe0' User entered 'No (N)'	System	09 Aug 2020 11:56:06
	System	09 Aug 2020 11:56:06

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:56:01', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '16bebd17-9fa5-49ff-8274-0b0005e4cfe0'	System	09 Aug 2020 11:56:06
User entered 'None (1)'	System	09 Aug 2020 11:56:06

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:56:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '16bebd17-9fa5-49ff-8274-0b0005e4cfe0' User entered '09 Aug 2020 07:56'	System	09 Aug 2020 11:56:06
	System	09 Aug 2020 11:56:06

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'None (0)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:51', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'None (0)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:53', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'None (0)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:55', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'None (0)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'None (0)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:06:59', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'None (0)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:07:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered 'No (N)'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T09:07:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4725b3e8-2bb5-4905-ae7b-c8246697865a' User entered '02 Aug 2020 09:07'	System	02 Aug 2020 13:07:21
	System	02 Aug 2020 13:07:21

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 08:54'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 11:24'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 1, after vaccination (at home)'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered 'None (0)'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:54', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef'	System	02 Aug 2020 21:18:12
User entered 'No interference with activity (1)'	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:17:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered 'None (0)'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:18:01', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered 'None (0)'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:18:03', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered 'None (0)'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:18:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered 'None (0)'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:18:08', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered 'No (N)'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-02T17:18:10', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'fb41a455-605a-458f-b774-f469c5631bef' User entered '02 Aug 2020 17:18'	System	02 Aug 2020 21:18:12
	System	02 Aug 2020 21:18:12

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Aug 2020 12:19'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 2'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113'	System	03 Aug 2020 23:56:25
User entered 'No interference with activity (1)'	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:08', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113'	System	03 Aug 2020 23:56:25
User entered 'No interference with activity (1)'	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113' User entered 'None (0)'	System	03 Aug 2020 23:56:25
	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:13', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113' User entered 'None (0)'	System	03 Aug 2020 23:56:25
	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113' User entered 'None (0)'	System	03 Aug 2020 23:56:25
	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113' User entered 'None (0)'	System	03 Aug 2020 23:56:25
	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113' User entered 'No (N)'	System	03 Aug 2020 23:56:25
	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-03T19:56:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e3ef530-80ea-463c-89bd-f8a987042113' User entered '03 Aug 2020 19:56'	System	03 Aug 2020 23:56:25
	System	03 Aug 2020 23:56:25

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 3'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'No interference with activity (1)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'No interference with activity (1)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'None (0)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:13', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'None (0)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'None (0)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'None (0)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered 'No (N)'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-04T17:12:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cc14fae7-525b-415c-a6c8-29a9aa5969a2'	System	04 Aug 2020 21:12:23
User entered '04 Aug 2020 17:12'	System	04 Aug 2020 21:12:23

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '05 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 4'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:08:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db'	System	06 Aug 2020 01:09:38
User entered 'No interference with activity (1)'	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:08:47', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db'	System	06 Aug 2020 01:09:38
User entered 'No interference with activity (1)'	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:08:53', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db' User entered 'None (0)'	System	06 Aug 2020 01:09:38
	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:08:56', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db' User entered 'None (0)'	System	06 Aug 2020 01:09:38
	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:08:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db' User entered 'None (0)'	System	06 Aug 2020 01:09:38
	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:13', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db' User entered 'None (0)'	System	06 Aug 2020 01:09:38
	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db' User entered 'No (N)'	System	06 Aug 2020 01:09:38
	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-05T21:09:33', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c0fe322d-bf6c-443a-8e52-48f607cf98db' User entered '05 Aug 2020 21:09'	System	06 Aug 2020 01:09:38
	System	06 Aug 2020 01:09:38

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '05 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '06 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 5'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec' User entered 'None (0)'	System	06 Aug 2020 23:06:46
	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec'	System	06 Aug 2020 23:06:46
User entered 'No interference with activity (1)'	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec' User entered 'None (0)'	System	06 Aug 2020 23:06:46
	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec' User entered 'None (0)'	System	06 Aug 2020 23:06:46
	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec' User entered 'None (0)'	System	06 Aug 2020 23:06:46
	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec'	System	06 Aug 2020 23:06:46
User entered 'None (0)'	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:27', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec'	System	06 Aug 2020 23:06:46
User entered 'No (N)'	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-06T19:06:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a8c1d896-c05a-4250-a5e0-317e4d3eccec'	System	06 Aug 2020 23:06:46
User entered '06 Aug 2020 19:06'	System	06 Aug 2020 23:06:46

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '06 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '07 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 6'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a'	System	08 Aug 2020 02:37:19
User entered 'No interference with activity (1)'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a'	System	08 Aug 2020 02:37:19
User entered 'No interference with activity (1)'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:08', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a' User entered 'None (0)'	System	08 Aug 2020 02:37:19
	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:10', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a' User entered 'None (0)'	System	08 Aug 2020 02:37:19
	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a' User entered 'None (0)'	System	08 Aug 2020 02:37:19
	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:13', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a' User entered 'None (0)'	System	08 Aug 2020 02:37:19
	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:14', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a' User entered 'No (N)'	System	08 Aug 2020 02:37:19
	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-07T22:37:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b3a5036d-278b-4bca-96e2-8527193b2c8a' User entered '07 Aug 2020 22:37'	System	08 Aug 2020 02:37:19
	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '07 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '08 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 7'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:34', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f'	System	09 Aug 2020 11:55:55
User entered 'No interference with activity (1)'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f'	System	09 Aug 2020 11:55:55
User entered 'No interference with activity (1)'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:37', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f' User entered 'None (0)'	System	09 Aug 2020 11:55:55
	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f' User entered 'None (0)'	System	09 Aug 2020 11:55:55
	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:40', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f' User entered 'None (0)'	System	09 Aug 2020 11:55:55
	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:42', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f' User entered 'None (0)'	System	09 Aug 2020 11:55:55
	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:49', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f' User entered 'No (N)'	System	09 Aug 2020 11:55:55
	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T07:55:52', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '52c5b627-e367-4f0c-b514-042fd066485f' User entered '09 Aug 2020 07:55'	System	09 Aug 2020 11:55:55
	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '08 Aug 2020 12:00'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '09 Aug 2020 11:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	08 Aug 2020 02:37:19
User entered 'Day 8'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:25:29

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T19:54:52', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '56f364dd-0c33-4c46-be3a-ed6f1a2024ce' User entered 'None (0)'	System	09 Aug 2020 23:54:58
	System	09 Aug 2020 23:54:58

US3722025

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T19:54:56', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '56f364dd-0c33-4c46-be3a-ed6f1a2024ce' User entered '09 Aug 2020 19:54'	System	09 Aug 2020 23:54:58
	System	09 Aug 2020 23:54:58

US3722025

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	08 Aug 2020 02:37:19
User entered 'Day 8'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:25:29

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T19:55:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e893e2b0-0a97-4a15-ab48-8d1b81b1db9c'	System	09 Aug 2020 23:55:05
User entered 'No interference with activity (1)'	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T19:55:02', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e893e2b0-0a97-4a15-ab48-8d1b81b1db9c' User entered '09 Aug 2020 19:55'	System	09 Aug 2020 23:55:05
	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	09 Aug 2020 11:55:55
User entered 'Day 9'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:25:29

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-10T22:57:31', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6885f428-f1ae-4dfa-b003-85b4f8cbfccd'	System	11 Aug 2020 02:57:37
User entered 'No interference with activity (1)'	System	11 Aug 2020 02:57:37

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-10T22:57:33', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6885f428-f1ae-4dfa-b003-85b4f8cbfccd'	System	11 Aug 2020 02:57:37
User entered '10 Aug 2020 22:57'	System	11 Aug 2020 02:57:37

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	09 Aug 2020 23:55:05
User entered 'Day 10'	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:25:29

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-11T23:59:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ddc29c88-8ea5-4289-9af5-ab3e9e614942'	System	12 Aug 2020 03:59:27
User entered 'None (0)'	System	12 Aug 2020 03:59:27

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-11T23:59:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ddc29c88-8ea5-4289-9af5-ab3e9e614942'	System	12 Aug 2020 03:59:27
User entered '11 Aug 2020 23:59'	System	12 Aug 2020 03:59:27

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	08 Aug 2020 02:37:19
User entered 'Day 8'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T19:55:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5e36f71e-4839-4000-a708-624caf54d0ab' User entered 'No (N)'	System	09 Aug 2020 23:55:11
	System	09 Aug 2020 23:55:11

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-09T19:55:07', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5e36f71e-4839-4000-a708-624caf54d0ab'	System	09 Aug 2020 23:55:11
User entered '09 Aug 2020 19:55'	System	09 Aug 2020 23:55:11

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 02:37:19

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
DataPoint Activated.	System	09 Aug 2020 23:55:05
DataPoint Inactivated.	System	09 Aug 2020 23:54:58
Data entry locked.	System	09 Aug 2020 11:55:55
User entered 'Day 9'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-10T22:57:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '348d595c-50e4-40e3-8aa2-fd524c7261af'	System	11 Aug 2020 02:57:42
User entered 'No (N)'	System	11 Aug 2020 02:57:42
DataPoint Activated.	System	09 Aug 2020 23:55:05
DataPoint Inactivated.	System	09 Aug 2020 23:54:58

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-10T22:57:37', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '348d595c-50e4-40e3-8aa2-fd524c7261af'	System	11 Aug 2020 02:57:42
User entered '10 Aug 2020 22:57'	System	11 Aug 2020 02:57:42
DataPoint Activated.	System	09 Aug 2020 23:55:05
DataPoint Inactivated.	System	09 Aug 2020 23:54:58

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
DataPoint Activated.	System	09 Aug 2020 23:55:05
DataPoint Inactivated.	System	09 Aug 2020 23:54:58
User entered '10 Aug 2020 12:00'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
DataPoint Activated.	System	09 Aug 2020 23:55:05
DataPoint Inactivated.	System	09 Aug 2020 23:54:58
User entered '11 Aug 2020 11:59'	System	09 Aug 2020 11:55:55

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	09 Aug 2020 23:55:05
User entered 'Day 10'	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-11T23:59:27', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f96710c4-d9d7-4450-a63a-d05c21135e8a' User entered 'No (N)'	System	12 Aug 2020 03:59:30
	System	12 Aug 2020 03:59:30

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-11T23:59:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f96710c4-d9d7-4450-a63a-d05c21135e8a'	System	12 Aug 2020 03:59:30
User entered '11 Aug 2020 23:59'	System	12 Aug 2020 03:59:30

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '11 Aug 2020 12:00'	System	09 Aug 2020 23:55:05

US3722025

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '12 Aug 2020 11:59'	System	09 Aug 2020 23:55:05

US3722025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 00:38:09

US3722025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '9 Aug 2020'	Amy Ford (b) (4)	10 Aug 2020 00:38:09

US3722025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	10 Aug 2020 00:38:09

US3722025

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:38:09

US3722025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 00:38:17

US3722025

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered '1'	System	10 Aug 2020 00:38:17

US3722025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	16 Aug 2020 16:36:21

US3722025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '16 Aug 2020'	Amy Ford (b) (4)	16 Aug 2020 16:36:21

US3722025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	16 Aug 2020 16:36:21

US3722025

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Amy Ford (b) (4)	16 Aug 2020 16:36:21

US3722025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	16 Aug 2020 16:36:11

US3722025

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:35:46
User entered 'I'	System	16 Aug 2020 16:36:11

US3722025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	27 Aug 2020 12:48:07

US3722025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '26 Aug 2020'	Kayla Peay (b) (4)	27 Aug 2020 12:48:07

US3722025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	27 Aug 2020 12:48:07

US3722025

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	27 Aug 2020 12:48:07

US3722025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	27 Aug 2020 12:47:59

US3722025

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'I'	System	27 Aug 2020 12:47:59

US3722025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 20:25:05

US3722025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 13:01:33
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Per protocol subjects are in window ' (Site from System).	Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:26:02
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	28 Aug 2020 20:25:05
User entered '28 Aug 2020'	Sara Poff (b) (4) (b) (4)	28 Aug 2020 20:25:05

US3722025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Clinic (Clinic)'	Sara Poff (b) (4)	28 Aug 2020 20:25:05

US3722025

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'VISIT2'	System	28 Aug 2020 20:25:05

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User accepted default value 'Pre-Dose (PREDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '15:19'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '28 Aug 2020 15:19'	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '98.7' F	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '90'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'bpm'	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '18'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'breaths/min'	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '121'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'mmHg'	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '83'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'mmHg'	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User accepted default value 'Post-Dose (POSTDOSE)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 12:21:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 12:21:19
User entered '16:38' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:21:19
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:04:14
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '28 Aug 2020 16:38'	System	31 Aug 2020 12:21:19
User entered empty.	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Data is required. Please provide.' (Site from System).	System	31 Aug 2020 12:21:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 12:21:19
User entered '98.4' F reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:21:19
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Aug 2020 20:04:14
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 12:21:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 12:21:19
User entered '79' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:21:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 20:04:14
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14
	(b) (4)	

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'bpm'	System	31 Aug 2020 12:21:19
User entered empty.	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 12:21:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 12:21:19
User entered '18' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:21:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 20:04:14
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14
	(b) (4)	

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'breaths/min'	System	31 Aug 2020 12:21:19
User entered empty.	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 12:21:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 12:21:19
User entered '100' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:21:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 20:04:14
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14
	(b) (4)	

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'mmHg'	System	31 Aug 2020 12:21:19
User entered empty.	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	31 Aug 2020 12:21:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		31 Aug 2020 12:21:19
User entered '71' reason for change: Data Entry Error	Kayla Peay (b) (4)	31 Aug 2020 12:21:19
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Aug 2020 20:04:14
User entered empty.	Kayla Peay (b) (4)	28 Aug 2020 20:04:14
	(b) (4)	

US3722025

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'mmHg'	System	31 Aug 2020 12:21:19
User entered empty.	System	28 Aug 2020 20:04:14

US3722025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:20

US3722025

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:04:20

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Urine (URINE)'	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Negative (NEGATIVE)'	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'No (N)'	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:25:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered empty.	System	31 Aug 2020 12:21:32

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Sara Poff (b) (4)	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Sara Poff (b) (4)	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Sara Poff (b) (4)	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '16:08'	Sara Poff (b) (4)	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '28 Aug 2020 16:08'	System	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Left Arm (LEFT ARM)'	Sara Poff (b) (4)	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'ONCE'	System	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:25:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 20:26:29

US3722025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:38

US3722025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:04:38

US3722025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '15:41'	Kayla Peay (b) (4)	28 Aug 2020 20:04:38

US3722025

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '28 Aug 2020 15:41'	System	28 Aug 2020 20:04:38

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:25:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '28 Aug 2020'	Kayla Peay (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '15:37'	Kayla Peay (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:25:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '28 Aug 2020 15:37'	System	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kayla Peay (b) (4) (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '15:37'	Kayla Peay (b) (4)	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:25:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '28 Aug 2020 15:37'	System	28 Aug 2020 20:04:54

US3722025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Sara Poff (b) (4)	28 Aug 2020 20:32:16

US3722025

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '1'	System	28 Aug 2020 20:32:16

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:35:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '45abbdfa-55c9-4bf4-9c07-48750cdb0194'	System	28 Aug 2020 20:35:36
User entered 'Yes (Y)'	System	28 Aug 2020 20:35:36

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:35:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '45abbdfa-55c9-4bf4-9c07-48750cdb0194' User entered '98.4'	System	28 Aug 2020 20:35:36
	System	28 Aug 2020 20:35:36

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:35:28', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '45abbdfa-55c9-4bf4-9c07-48750cdb0194'	System	28 Aug 2020 20:35:36
User entered 'No (N)'	System	28 Aug 2020 20:35:36

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:35:32', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '45abbdfa-55c9-4bf4-9c07-48750cdb0194'	System	28 Aug 2020 20:35:36
User entered '28 Aug 2020 16:35'	System	28 Aug 2020 20:35:36

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 16:28'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 18:58'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:34', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '061b4a45-08b9-44bf-a8eb-3bfc336e6e5'	System	29 Aug 2020 12:17:44
User entered 'Yes (Y)'	System	29 Aug 2020 12:17:44

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:38', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '061b4a45-08b9-44bf-a8eb-3bfc336e6e5' User entered '97.9'	System	29 Aug 2020 12:17:44
	System	29 Aug 2020 12:17:44

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '061b4a45-08b9-44bf-a8eb-3bfc336e6e5'	System	29 Aug 2020 12:17:44
User entered 'No (N)'	System	29 Aug 2020 12:17:44

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '061b4a45-08b9-44bf-a8eb-3bfc336e6e5' User entered '29 Aug 2020 08:17'	System	29 Aug 2020 12:17:44
	System	29 Aug 2020 12:17:44

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 19:53'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 2'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T22:53:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b9a0cfb9-b8fe-4a16-b36e-1e6e2f98ff01' User entered 'Yes (Y)'	System	30 Aug 2020 02:53:31
	System	30 Aug 2020 02:53:31

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T22:53:10', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b9a0cfb9-b8fe-4a16-b36e-1e6e2f98ff01' User entered '95.8'	System	30 Aug 2020 02:53:31
	System	30 Aug 2020 02:53:31

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T22:53:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b9a0cfb9-b8fe-4a16-b36e-1e6e2f98ff01'	System	30 Aug 2020 02:53:31
User entered 'Yes (Y)'	System	30 Aug 2020 02:53:31

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 08:14:54
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Amy Ford (b) (4)	21 Sep 2020 17:50:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T22:53:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b9a0cfb9-b8fe-4a16-b36e-1e6e2f98ff01'	(b) (4)	
User entered '1'	System	30 Aug 2020 02:53:31
	System	30 Aug 2020 02:53:31
	System	30 Aug 2020 02:53:31

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T22:53:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b9a0cfb9-b8fe-4a16-b36e-1e6e2f98ff01' User entered '0'	System	30 Aug 2020 02:53:31
	System	30 Aug 2020 02:53:31

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T22:53:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'b9a0cfb9-b8fe-4a16-b36e-1e6e2f98ff01' User entered '29 Aug 2020 22:53'	System	30 Aug 2020 02:53:31
	System	30 Aug 2020 02:53:31

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 3'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:13:42', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '156a0a1e-e001-4bee-94a9-8c35302d782d' User entered 'Yes (Y)'	System	31 Aug 2020 00:16:05
	System	31 Aug 2020 00:16:05

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:14:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '156a0a1e-e001-4bee-94a9-8c35302d782d' User entered '96.5'	System	31 Aug 2020 00:16:05
	System	31 Aug 2020 00:16:05

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:14:51', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '156a0a1e-e001-4bee-94a9-8c35302d782d' User entered 'No (N)'	System	31 Aug 2020 00:16:05
	System	31 Aug 2020 00:16:05

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:14:53', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '156a0a1e-e001-4bee-94a9-8c35302d782d' User entered '30 Aug 2020 20:14'	System	31 Aug 2020 00:16:05
	System	31 Aug 2020 00:16:05

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 4'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:25', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ca2b7221-9ae5-4c38-86e4-49665bbe2ca1' User entered 'Yes (Y)'	System	01 Sep 2020 03:13:37
	System	01 Sep 2020 03:13:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ca2b7221-9ae5-4c38-86e4-49665bbe2ca1' User entered '97.5'	System	01 Sep 2020 03:13:37
	System	01 Sep 2020 03:13:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:32', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ca2b7221-9ae5-4c38-86e4-49665bbe2ca1' User entered 'No (N)'	System	01 Sep 2020 03:13:37
	System	01 Sep 2020 03:13:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:35', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ca2b7221-9ae5-4c38-86e4-49665bbe2ca1'	System	01 Sep 2020 03:13:37
User entered '31 Aug 2020 23:13'	System	01 Sep 2020 03:13:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 5'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T23:08:25', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '048892dc-2147-4286-9645-e1658110d6d0'	System	02 Sep 2020 03:08:37
User entered 'Yes (Y)'	System	02 Sep 2020 03:08:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T23:08:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '048892dc-2147-4286-9645-e1658110d6d0' User entered '96.0'	System	02 Sep 2020 03:08:37
	System	02 Sep 2020 03:08:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T23:08:34', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '048892dc-2147-4286-9645-e1658110d6d0'	System	02 Sep 2020 03:08:37
User entered 'No (N)'	System	02 Sep 2020 03:08:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T23:08:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '048892dc-2147-4286-9645-e1658110d6d0'	System	02 Sep 2020 03:08:37
User entered '01 Sep 2020 23:08'	System	02 Sep 2020 03:08:37

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 6'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e12aa10f-dcd4-414b-b7a6-d98109ee2c53' User entered 'Yes (Y)'	System	02 Sep 2020 22:28:48
	System	02 Sep 2020 22:28:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:28:26', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e12aa10f-dcd4-414b-b7a6-d98109ee2c53' User entered '97.7'	System	02 Sep 2020 22:28:48
	System	02 Sep 2020 22:28:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:28:28', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e12aa10f-dcd4-414b-b7a6-d98109ee2c53'	System	02 Sep 2020 22:28:48
User entered 'No (N)'	System	02 Sep 2020 22:28:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:28:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e12aa10f-dcd4-414b-b7a6-d98109ee2c53'	System	02 Sep 2020 22:28:48
User entered '02 Sep 2020 18:28'	System	02 Sep 2020 22:28:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 7'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6c788130-9b97-409a-9ef2-67e1cd3bf925'	System	04 Sep 2020 02:42:48
User entered 'Yes (Y)'	System	04 Sep 2020 02:42:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6c788130-9b97-409a-9ef2-67e1cd3bf925' User entered '97.0'	System	04 Sep 2020 02:42:48
	System	04 Sep 2020 02:42:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:42', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6c788130-9b97-409a-9ef2-67e1cd3bf925'	System	04 Sep 2020 02:42:48
User entered 'No (N)'	System	04 Sep 2020 02:42:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6c788130-9b97-409a-9ef2-67e1cd3bf925'	System	04 Sep 2020 02:42:48
User entered '03 Sep 2020 22:42'	System	04 Sep 2020 02:42:48

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:35:35', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '14a6376f-89e5-4727-b9d3-e9bf9aadd822'	System	28 Aug 2020 20:36:43
User entered 'None (1)'	System	28 Aug 2020 20:36:43

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:25', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '14a6376f-89e5-4727-b9d3-e9bf9aadd822'	System	28 Aug 2020 20:36:43
User entered 'No (N)'	System	28 Aug 2020 20:36:43

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:35', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '14a6376f-89e5-4727-b9d3-e9bf9aadd822'	System	28 Aug 2020 20:36:43
User entered 'No (N)'	System	28 Aug 2020 20:36:43

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '14a6376f-89e5-4727-b9d3-e9bf9aadd822'	System	28 Aug 2020 20:36:43
User entered 'None (1)'	System	28 Aug 2020 20:36:43

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '14a6376f-89e5-4727-b9d3-e9bf9aadd822' User entered '28 Aug 2020 16:36'	System	28 Aug 2020 20:36:43
	System	28 Aug 2020 20:36:43

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 16:28'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 18:58'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:18:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'baa273ac-7c03-442f-82b0-6f866c7c0757'	System	29 Aug 2020 12:19:09
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 12:19:09

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:18:37', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'baa273ac-7c03-442f-82b0-6f866c7c0757'	System	29 Aug 2020 12:19:09
User entered 'No (N)'	System	29 Aug 2020 12:19:09

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:18:51', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'baa273ac-7c03-442f-82b0-6f866c7c0757'	System	29 Aug 2020 12:19:09
User entered 'No (N)'	System	29 Aug 2020 12:19:09

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:19:03', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'baa273ac-7c03-442f-82b0-6f866c7c0757'	System	29 Aug 2020 12:19:09
User entered 'None (1)'	System	29 Aug 2020 12:19:09

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:19:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'baa273ac-7c03-442f-82b0-6f866c7c0757'	System	29 Aug 2020 12:19:09
User entered '29 Aug 2020 08:19'	System	29 Aug 2020 12:19:09

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 19:53'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 2'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:20:53', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '336eddde-4717-45a4-b250-633af608a6ff'	System	30 Aug 2020 00:21:37
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 00:21:37

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:20', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '336eddde-4717-45a4-b250-633af608a6ff'	System	30 Aug 2020 00:21:37
User entered 'No (N)'	System	30 Aug 2020 00:21:37

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:26', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '336eddde-4717-45a4-b250-633af608a6ff' User entered 'No (N)'	System	30 Aug 2020 00:21:37
	System	30 Aug 2020 00:21:37

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:33', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '336eddde-4717-45a4-b250-633af608a6ff' User entered 'None (1)'	System	30 Aug 2020 00:21:37
	System	30 Aug 2020 00:21:37

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:35', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '336eddde-4717-45a4-b250-633af608a6ff' User entered '29 Aug 2020 20:21'	System	30 Aug 2020 00:21:37
	System	30 Aug 2020 00:21:37

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 3'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2b697c2d-478f-4a6d-a0f7-9b41d05c63ef'	System	31 Aug 2020 00:16:44
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 00:16:44

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2b697c2d-478f-4a6d-a0f7-9b41d05c63ef' User entered 'No (N)'	System	31 Aug 2020 00:16:44
	System	31 Aug 2020 00:16:44

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2b697c2d-478f-4a6d-a0f7-9b41d05c63ef' User entered 'No (N)'	System	31 Aug 2020 00:16:44
	System	31 Aug 2020 00:16:44

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:32', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2b697c2d-478f-4a6d-a0f7-9b41d05c63ef' User entered 'None (1)'	System	31 Aug 2020 00:16:44
	System	31 Aug 2020 00:16:44

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:51', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2b697c2d-478f-4a6d-a0f7-9b41d05c63ef' User entered '30 Aug 2020 20:15'	System	31 Aug 2020 00:16:44
	System	31 Aug 2020 00:16:44

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 4'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd8ed5000-937d-4fe6-8661-d6cb41a31201'	System	01 Sep 2020 03:14:00
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 03:14:00

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:46', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd8ed5000-937d-4fe6-8661-d6cb41a31201' User entered 'No (N)'	System	01 Sep 2020 03:14:00
	System	01 Sep 2020 03:14:00

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd8ed5000-937d-4fe6-8661-d6cb41a31201'	System	01 Sep 2020 03:14:00
User entered 'No (N)'	System	01 Sep 2020 03:14:00

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:52', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd8ed5000-937d-4fe6-8661-d6cb41a31201'	System	01 Sep 2020 03:14:00
User entered 'None (1)'	System	01 Sep 2020 03:14:00

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:55', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'd8ed5000-937d-4fe6-8661-d6cb41a31201'	System	01 Sep 2020 03:14:00
User entered '31 Aug 2020 23:13'	System	01 Sep 2020 03:14:00

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 5'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:02:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'efb019c2-5018-4013-9f1f-4d338441ebfc' User entered 'None (1)'	System	02 Sep 2020 02:02:21
	System	02 Sep 2020 02:02:21

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:02:12', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'efb019c2-5018-4013-9f1f-4d338441ebfc'	System	02 Sep 2020 02:02:21
User entered 'No (N)'	System	02 Sep 2020 02:02:21

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:02:14', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'efb019c2-5018-4013-9f1f-4d338441ebfc' User entered 'No (N)'	System	02 Sep 2020 02:02:21
	System	02 Sep 2020 02:02:21

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:02:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'efb019c2-5018-4013-9f1f-4d338441ebfc'	System	02 Sep 2020 02:02:21
User entered 'None (1)'	System	02 Sep 2020 02:02:21

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:02:18', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'efb019c2-5018-4013-9f1f-4d338441ebfc' User entered '01 Sep 2020 22:02'	System	02 Sep 2020 02:02:21
	System	02 Sep 2020 02:02:21

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 6'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:27', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1d2c5ba3-2ed6-457e-afe0-fb08cf14624b' User entered 'None (1)'	System	02 Sep 2020 22:27:34
	System	02 Sep 2020 22:27:34

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:29', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1d2c5ba3-2ed6-457e-afe0-fb08cf14624b' User entered 'No (N)'	System	02 Sep 2020 22:27:34
	System	02 Sep 2020 22:27:34

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1d2c5ba3-2ed6-457e-afe0-fb08cf14624b' User entered 'No (N)'	System	02 Sep 2020 22:27:34
	System	02 Sep 2020 22:27:34

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:31', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1d2c5ba3-2ed6-457e-afe0-fb08cf14624b' User entered 'None (1)'	System	02 Sep 2020 22:27:34
	System	02 Sep 2020 22:27:34

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:33', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1d2c5ba3-2ed6-457e-afe0-fb08cf14624b' User entered '02 Sep 2020 18:27'	System	02 Sep 2020 22:27:34
	System	02 Sep 2020 22:27:34

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 7'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '984bc22a-9b89-433a-a734-c0e8679e65a6'	System	04 Sep 2020 02:42:30
User entered 'None (1)'	System	04 Sep 2020 02:42:30

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '984bc22a-9b89-433a-a734-c0e8679e65a6'	System	04 Sep 2020 02:42:30
User entered 'No (N)'	System	04 Sep 2020 02:42:30

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '984bc22a-9b89-433a-a734-c0e8679e65a6'	System	04 Sep 2020 02:42:30
User entered 'No (N)'	System	04 Sep 2020 02:42:30

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '984bc22a-9b89-433a-a734-c0e8679e65a6'	System	04 Sep 2020 02:42:30
User entered 'None (1)'	System	04 Sep 2020 02:42:30

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:26', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '984bc22a-9b89-433a-a734-c0e8679e65a6' User entered '03 Sep 2020 22:42'	System	04 Sep 2020 02:42:30
	System	04 Sep 2020 02:42:30

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:45', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'None (0)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:47', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'None (0)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:49', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'None (0)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:55', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'None (0)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'None (0)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:36:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'None (0)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:37:02', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered 'No (N)'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-28T16:37:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '989b5746-0dab-488a-a080-1852aa62f151' User entered '28 Aug 2020 16:37'	System	28 Aug 2020 20:37:08
	System	28 Aug 2020 20:37:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 16:28'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 18:58'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:47', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered 'None (0)'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:50', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered 'None (0)'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:54', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered 'None (0)'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered 'None (0)'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:17:59', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered 'None (0)'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:18:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered 'None (0)'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:18:02', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056'	System	29 Aug 2020 12:18:08
User entered 'No (N)'	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T08:18:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '5c1d7440-2ca5-4fc6-abbd-f52f61728056' User entered '29 Aug 2020 08:18'	System	29 Aug 2020 12:18:08
	System	29 Aug 2020 12:18:08

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '28 Aug 2020 19:53'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 2'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f'	System	30 Aug 2020 00:22:01
User entered 'No interference with activity (1)'	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:42', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f'	System	30 Aug 2020 00:22:01
User entered 'Some interference with activity (2)'	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:45', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f'	System	30 Aug 2020 00:22:01
User entered 'Some interference with activity (2)'	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:49', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f' User entered 'No interference with activity (1)'	System	30 Aug 2020 00:22:01
	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:51', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f' User entered 'None (0)'	System	30 Aug 2020 00:22:01
	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:53', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f'	System	30 Aug 2020 00:22:01
User entered 'No interference with activity (1)'	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:56', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f' User entered 'No (N)'	System	30 Aug 2020 00:22:01
	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-29T20:21:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '2ca77137-b02f-487f-9ca5-f386542b545f' User entered '29 Aug 2020 20:21'	System	30 Aug 2020 00:22:01
	System	30 Aug 2020 00:22:01

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 3'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:14:56', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550' User entered 'None (0)'	System	31 Aug 2020 00:16:12
	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:14:59', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550'	System	31 Aug 2020 00:16:12
User entered 'No interference with activity (1)'	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:01', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550'	System	31 Aug 2020 00:16:12
User entered 'None (0)'	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:03', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550' User entered 'None (0)'	System	31 Aug 2020 00:16:12
	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550' User entered 'None (0)'	System	31 Aug 2020 00:16:12
	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550' User entered 'None (0)'	System	31 Aug 2020 00:16:12
	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:07', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550'	System	31 Aug 2020 00:16:12
User entered 'No (N)'	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-30T20:15:10', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '08152e5d-265f-490f-90bd-517ae8ff4550'	System	31 Aug 2020 00:16:12
User entered '30 Aug 2020 20:15'	System	31 Aug 2020 00:16:12

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 4'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:13:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6'	System	01 Sep 2020 03:14:18
User entered 'No interference with activity (1)'	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6'	System	01 Sep 2020 03:14:18
User entered 'No interference with activity (1)'	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6' User entered 'None (0)'	System	01 Sep 2020 03:14:18
	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:08', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6' User entered 'None (0)'	System	01 Sep 2020 03:14:18
	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:10', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6' User entered 'None (0)'	System	01 Sep 2020 03:14:18
	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:12', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6' User entered 'None (0)'	System	01 Sep 2020 03:14:18
	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6' User entered 'No (N)'	System	01 Sep 2020 03:14:18
	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-08-31T23:14:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8249afb4-529f-4ace-b0ba-4fa3228044d6'	System	01 Sep 2020 03:14:18
User entered '31 Aug 2020 23:14'	System	01 Sep 2020 03:14:18

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 5'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'None (0)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:41', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'None (0)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'None (0)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'None (0)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:46', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'None (0)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:49', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'None (0)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:50', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered 'No (N)'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-01T22:01:53', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1eda04c-ea24-4c1e-abac-818c8602f528'	System	02 Sep 2020 02:01:58
User entered '01 Sep 2020 22:01'	System	02 Sep 2020 02:01:58

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 6'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:16', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'None (0)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'None (0)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:18', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'None (0)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:19', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'None (0)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'None (0)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'None (0)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered 'No (N)'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-02T18:27:25', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9d8065d6-e3d7-4ac1-9f6b-b8f2e5a64538' User entered '02 Sep 2020 18:27'	System	02 Sep 2020 22:27:29
	System	02 Sep 2020 22:27:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	28 Aug 2020 20:26:29
User entered 'Day 7'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:01', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'None (0)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:03', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'None (0)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'None (0)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'None (0)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:06', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'None (0)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:07', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'None (0)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:09', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered 'No (N)'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-09-03T22:42:12', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'dc77eef6-b8e5-4695-a382-82428cc477bd' User entered '03 Sep 2020 22:42'	System	04 Sep 2020 02:42:15
	System	04 Sep 2020 02:42:15

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 20:26:29

US3722025

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:25:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 20:26:29

US3722025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	08 Sep 2020 01:12:45

US3722025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '7 Sep 2020'	Amy Ford (b) (4)	08 Sep 2020 01:12:45

US3722025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	08 Sep 2020 01:12:45

US3722025

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Amy Ford (b) (4)	08 Sep 2020 01:12:45

US3722025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	08 Sep 2020 01:12:50

US3722025

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '1'	System	08 Sep 2020 01:12:50

US3722025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	11 Sep 2020 16:01:44

US3722025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '11 Sep 2020'	Amy Ford (b) (4)	11 Sep 2020 16:01:44

US3722025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Contact Made (CONTACT MADE)'	Amy Ford (b) (4)	11 Sep 2020 16:01:44

US3722025

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Amy Ford (b) (4)	11 Sep 2020 16:01:44

US3722025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Amy Ford (b) (4)	11 Sep 2020 16:01:48

US3722025

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'I'	System	11 Sep 2020 16:01:48

US3722025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	18 Sep 2020 17:33:59

US3722025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '18 Sep 2020'	Kayla Peay (b) (4)	18 Sep 2020 17:33:59

US3722025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Contact Made (CONTACT MADE)'	Kayla Peay (b) (4)	18 Sep 2020 17:33:59

US3722025

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	18 Sep 2020 17:33:59

US3722025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	18 Sep 2020 17:34:03

US3722025

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '1'	System	18 Sep 2020 17:34:03

US3722025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:55:55

US3722025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '29 Sep 2020'	Kayla Peay (b) (4)	29 Sep 2020 20:55:55

US3722025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Clinic (Clinic)'	Kayla Peay (b) (4)	29 Sep 2020 20:55:55

US3722025

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'VISIT3'	System	29 Sep 2020 20:55:55

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '29 Sep 2020'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '15:48'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '29 Sep 2020 15:48'	System	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '98' F	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Oral (Oral)'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered empty.	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '76'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'bpm'	System	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '18'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'breaths/min'	System	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '108'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'mmHg'	System	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '74'	Kayla Peay (b) (4)	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'mmHg'	System	29 Sep 2020 20:56:30

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10

US3722025

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10

US3722025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:56:40

US3722025

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '29 Sep 2020'	Kayla Peay (b) (4)	29 Sep 2020 20:56:40

US3722025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:56:47

US3722025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '29 Sep 2020'	Kayla Peay (b) (4)	29 Sep 2020 20:56:47

US3722025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered '15:56'	Kayla Peay (b) (4)	29 Sep 2020 20:56:47

US3722025

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '29 Sep 2020 15:56'	System	29 Sep 2020 20:56:47

US3722025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	24 Feb 2021 13:53:45
User entered 'Yes (Y)'	Kayla Peay (b) (4)	29 Sep 2020 20:56:50

US3722025

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered '1'	System	29 Sep 2020 20:56:50

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 64'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-05T16:04:39', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '93e1abbb-7d33-4f35-8b51-33666a696e1c' User entered 'No (N)'	System	05 Oct 2020 20:04:51
	System	05 Oct 2020 20:04:51

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-05T16:04:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '93e1abbb-7d33-4f35-8b51-33666a696e1c'	System	05 Oct 2020 20:04:51
User entered 'No (N)'	System	05 Oct 2020 20:04:51

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-05T16:04:46', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '93e1abbb-7d33-4f35-8b51-33666a696e1c' User entered '05 Oct 2020 16:04:46'	System	05 Oct 2020 20:04:51
	System	05 Oct 2020 20:04:51

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '02 Oct 2020 00:01'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '06 Oct 2020 23:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 71'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-11T17:12:43', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ba3eb686-7404-44a5-ad2d-ca52905b6c3d'	System	11 Oct 2020 21:12:51
User entered 'No (N)'	System	11 Oct 2020 21:12:51

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-11T17:12:46', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ba3eb686-7404-44a5-ad2d-ca52905b6c3d'	System	11 Oct 2020 21:12:51
User entered 'No (N)'	System	11 Oct 2020 21:12:51

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-11T17:12:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'ba3eb686-7404-44a5-ad2d-ca52905b6c3d' User entered '11 Oct 2020 17:12:48'	System	11 Oct 2020 21:12:51
	System	11 Oct 2020 21:12:51

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '09 Oct 2020 00:01'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '13 Oct 2020 23:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 78'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-16T00:01:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3e6c92f7-a7db-4e16-bca3-2d58b5de690d' User entered 'No (N)'	System	16 Oct 2020 04:01:37
	System	16 Oct 2020 04:01:37

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-16T00:01:28', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3e6c92f7-a7db-4e16-bca3-2d58b5de690d'	System	16 Oct 2020 04:01:37
User entered 'No (N)'	System	16 Oct 2020 04:01:37

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-10-16T00:01:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3e6c92f7-a7db-4e16-bca3-2d58b5de690d' User entered '16 Oct 2020 00:01:30'	System	16 Oct 2020 04:01:37
	System	16 Oct 2020 04:01:37

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '16 Oct 2020 00:01'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '20 Oct 2020 23:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 92'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-02T17:44:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f6ad98d8-f076-461f-a0dc-01b1bd3ee923'	System	02 Nov 2020 22:44:24
User entered 'No (N)'	System	02 Nov 2020 22:44:24

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-02T17:44:18', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f6ad98d8-f076-461f-a0dc-01b1bd3ee923'	System	02 Nov 2020 22:44:24
User entered 'No (N)'	System	02 Nov 2020 22:44:24

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-02T17:44:21', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f6ad98d8-f076-461f-a0dc-01b1bd3ee923' User entered '02 Nov 2020 17:44:21'	System	02 Nov 2020 22:44:24
	System	02 Nov 2020 22:44:24

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '30 Oct 2020 00:01'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '03 Nov 2020 23:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 99'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-10T12:03:20', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3f0fc8e9-8d07-47df-b2c9-877651a6412f' User entered 'No (N)'	System	10 Nov 2020 17:04:31
	System	10 Nov 2020 17:04:31

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-10T12:03:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3f0fc8e9-8d07-47df-b2c9-877651a6412f' User entered 'No (N)'	System	10 Nov 2020 17:04:31
	System	10 Nov 2020 17:04:31

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-10T12:03:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3f0fc8e9-8d07-47df-b2c9-877651a6412f' User entered '10 Nov 2020 12:03:24'	System	10 Nov 2020 17:04:31
	System	10 Nov 2020 17:04:31

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '06 Nov 2020 00:01'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '10 Nov 2020 23:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered 'Day 106'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-13T08:00:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '613451e9-1971-49ee-b97e-836e9ed22f43'	System	13 Nov 2020 13:00:27
User entered 'No (N)'	System	13 Nov 2020 13:00:27

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-13T08:00:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '613451e9-1971-49ee-b97e-836e9ed22f43'	System	13 Nov 2020 13:00:27
User entered 'No (N)'	System	13 Nov 2020 13:00:27

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-13T08:00:24', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '613451e9-1971-49ee-b97e-836e9ed22f43' User entered '13 Nov 2020 08:00:24'	System	13 Nov 2020 13:00:27
	System	13 Nov 2020 13:00:27

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '13 Nov 2020 00:01'	System	02 Aug 2020 12:41:54

US3722025

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:44:07
Data entry locked.	System	02 Aug 2020 12:41:54
User entered '17 Nov 2020 23:59'	System	02 Aug 2020 12:41:54

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '17 Nov 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '21 Nov 2020 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-26T18:53:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f4b24448-c0b7-4f90-a4ed-9010769d7cf9' User entered 'No (N)'	System	26 Nov 2020 23:54:08

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-26T18:54:02', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f4b24448-c0b7-4f90-a4ed-9010769d7cf9'	System	26 Nov 2020 23:54:08
User entered 'No (N)'	System	26 Nov 2020 23:54:08

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-11-26T18:54:05', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f4b24448-c0b7-4f90-a4ed-9010769d7cf9' User entered '26 Nov 2020 18:54:05'	System	26 Nov 2020 23:54:08
	System	26 Nov 2020 23:54:08

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '24 Nov 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '28 Nov 2020 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-01T00:13:20', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a91b788b-f492-4d02-8046-cec05eafbc4c' User entered 'No (N)'	System	01 Dec 2020 05:13:32
	System	01 Dec 2020 05:13:32

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-01T00:13:22', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a91b788b-f492-4d02-8046-cec05eafbc4c' User entered 'No (N)'	System	01 Dec 2020 05:13:32

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-01T00:13:26', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'a91b788b-f492-4d02-8046-cec05eafbc4c' User entered '01 Dec 2020 00:13:26'	System	01 Dec 2020 05:13:32
	System	01 Dec 2020 05:13:32

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 Dec 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Dec 2020 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-10T12:35:44', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8e81cf0b-646c-4565-967e-a14ca14a0ce1' User entered 'No (N)'	System	10 Dec 2020 17:35:57
	System	10 Dec 2020 17:35:57

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-10T12:35:47', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8e81cf0b-646c-4565-967e-a14ca14a0ce1' User entered 'No (N)'	System	10 Dec 2020 17:35:57
	System	10 Dec 2020 17:35:57

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-10T12:35:49', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '8e81cf0b-646c-4565-967e-a14ca14a0ce1' User entered '10 Dec 2020 12:35:49'	System	10 Dec 2020 17:35:57
	System	10 Dec 2020 17:35:57

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 Dec 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Dec 2020 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-15T13:19:26', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6bf593d7-c14d-413f-8845-aeef3134e8f' User entered 'No (N)'	System	15 Dec 2020 18:19:35
	System	15 Dec 2020 18:19:35

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-15T13:19:30', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6bf593d7-c14d-413f-8845-aeef3134e8f' User entered 'No (N)'	System	15 Dec 2020 18:19:35

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-15T13:19:32', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6bf593d7-c14d-413f-8845-aeef3134e8f' User entered '15 Dec 2020 13:19:32'	System	15 Dec 2020 18:19:35
	System	15 Dec 2020 18:19:35

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '15 Dec 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Dec 2020 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-22T17:38:31', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c4cf218e-c8a3-45a8-b6e6-2ba274c70783' User entered 'No (N)'	System	22 Dec 2020 22:38:40
	System	22 Dec 2020 22:38:40

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-22T17:38:34', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c4cf218e-c8a3-45a8-b6e6-2ba274c70783'	System	22 Dec 2020 22:38:40
User entered 'No (N)'	System	22 Dec 2020 22:38:40

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-22T17:38:36', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'c4cf218e-c8a3-45a8-b6e6-2ba274c70783' User entered '22 Dec 2020 17:38:36'	System	22 Dec 2020 22:38:40
	System	22 Dec 2020 22:38:40

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '22 Dec 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Dec 2020 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-30T23:39:47', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cf61ac13-fe34-4657-8182-51b8ee72a6c4'	System	31 Dec 2020 04:39:59
User entered 'No (N)'	System	31 Dec 2020 04:39:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-30T23:39:55', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cf61ac13-fe34-4657-8182-51b8ee72a6c4'	System	31 Dec 2020 04:39:59
User entered 'No (N)'	System	31 Dec 2020 04:39:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2020-12-30T23:39:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'cf61ac13-fe34-4657-8182-51b8ee72a6c4' User entered '30 Dec 2020 23:39:57'	System	31 Dec 2020 04:39:59
	System	31 Dec 2020 04:39:59

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '29 Dec 2020 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Jan 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-07T13:53:23', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1a4c2de-c6bc-42ab-a0a7-5f78f88ea143'	System	07 Jan 2021 18:53:33
User entered 'No (N)'	System	07 Jan 2021 18:53:33

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-07T13:53:25', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1a4c2de-c6bc-42ab-a0a7-5f78f88ea143'	System	07 Jan 2021 18:53:33
User entered 'No (N)'	System	07 Jan 2021 18:53:33

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-07T13:53:27', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e1a4c2de-c6bc-42ab-a0a7-5f78f88ea143' User entered '07 Jan 2021 13:53:27'	System	07 Jan 2021 18:53:33

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Jan 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Jan 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-12T07:07:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3cc29359-2314-4760-9761-7b8fd2186998'	System	12 Jan 2021 12:08:06
User entered 'No (N)'	System	12 Jan 2021 12:08:06

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-12T07:07:59', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3cc29359-2314-4760-9761-7b8fd2186998'	System	12 Jan 2021 12:08:06
User entered 'No (N)'	System	12 Jan 2021 12:08:06

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-12T07:08:01', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '3cc29359-2314-4760-9761-7b8fd2186998' User entered '12 Jan 2021 07:08:01'	System	12 Jan 2021 12:08:06
	System	12 Jan 2021 12:08:06

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Jan 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Jan 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-19T19:08:04', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '80c62c72-eceb-421e-a797-cd389238f4cb' User entered 'No (N)'	System	20 Jan 2021 00:08:16
	System	20 Jan 2021 00:08:16

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-19T19:08:09', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '80c62c72-eceb-421e-a797-cd389238f4cb' User entered 'No (N)'	System	20 Jan 2021 00:08:16

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-19T19:08:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '80c62c72-eceb-421e-a797-cd389238f4cb' User entered '19 Jan 2021 19:08:11'	System	20 Jan 2021 00:08:16
	System	20 Jan 2021 00:08:16

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Jan 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Jan 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-26T01:18:11', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4fefcc70-4642-401d-b3bc-4bc4e27b51f0' User entered 'No (N)'	System	26 Jan 2021 06:18:22
	System	26 Jan 2021 06:18:22

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-26T01:18:15', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4fefcc70-4642-401d-b3bc-4bc4e27b51f0'	System	26 Jan 2021 06:18:22
User entered 'No (N)'	System	26 Jan 2021 06:18:22

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-01-26T01:18:17', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4fefcc70-4642-401d-b3bc-4bc4e27b51f0' User entered '26 Jan 2021 01:18:17'	System	26 Jan 2021 06:18:22
	System	26 Jan 2021 06:18:22

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Jan 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Jan 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-02T07:29:57', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1fc5205f-a109-4f9e-90a4-4cbeb89ca077' User entered 'No (N)'	System	02 Feb 2021 12:30:05
	System	02 Feb 2021 12:30:05

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-02T07:29:59', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1fc5205f-a109-4f9e-90a4-4cbeb89ca077'	System	02 Feb 2021 12:30:05
User entered 'No (N)'	System	02 Feb 2021 12:30:05

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-02T07:30:01', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '1fc5205f-a109-4f9e-90a4-4cbeb89ca077'	System	02 Feb 2021 12:30:05
User entered '02 Feb 2021 07:30:01'	System	02 Feb 2021 12:30:05

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Feb 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Feb 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-09T08:02:54', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9056651d-6606-4fac-a8a2-53a8c72c2ff1' User entered 'No (N)'	System	09 Feb 2021 13:03:02
	System	09 Feb 2021 13:03:02

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-09T08:02:56', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9056651d-6606-4fac-a8a2-53a8c72c2ff1' User entered 'No (N)'	System	09 Feb 2021 13:03:02
	System	09 Feb 2021 13:03:02

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-09T08:02:58', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9056651d-6606-4fac-a8a2-53a8c72c2ff1' User entered '09 Feb 2021 08:02:58'	System	09 Feb 2021 13:03:02
	System	09 Feb 2021 13:03:02

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Feb 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Feb 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-18T12:00:48', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e1ef962-7795-4d16-b290-05b77bc66e14' User entered 'No (N)'	System	18 Feb 2021 17:03:10
	System	18 Feb 2021 17:03:10

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-18T12:00:50', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e1ef962-7795-4d16-b290-05b77bc66e14' User entered 'No (N)'	System	18 Feb 2021 17:03:10
	System	18 Feb 2021 17:03:10

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-18T12:00:52', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '6e1ef962-7795-4d16-b290-05b77bc66e14' User entered '18 Feb 2021 12:00:52'	System	18 Feb 2021 17:03:10

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Feb 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Feb 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-23T23:12:33-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '82b9644c-dbc8-4edb-8af6-ab2db57466ea' User entered 'No (N)'	System	24 Feb 2021 04:12:40
	System	24 Feb 2021 04:12:40

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-23T23:12:35-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '82b9644c-dbc8-4edb-8af6-ab2db57466ea' User entered 'No (N)'	System	24 Feb 2021 04:12:40
	System	24 Feb 2021 04:12:40

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-02-23T23:12:37-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '82b9644c-dbc8-4edb-8af6-ab2db57466ea' User entered '24 Feb 2021 04:12:37'	System	24 Feb 2021 04:12:40
	System	24 Feb 2021 04:12:40

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Feb 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Feb 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-03T12:28:24-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '74a8c5ed-9c99-458a-ba67-0684575cf46e' User entered 'No (N)'	System	03 Mar 2021 17:38:23
	System	03 Mar 2021 17:38:23

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-03T12:28:26-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '74a8c5ed-9c99-458a-ba67-0684575cf46e'	System	03 Mar 2021 17:38:23
User entered 'No (N)'	System	03 Mar 2021 17:38:23

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-03T12:28:28-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '74a8c5ed-9c99-458a-ba67-0684575cf46e' User entered '03 Mar 2021 12:28:28'	System	03 Mar 2021 17:38:23
	System	03 Mar 2021 17:38:23

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Mar 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Mar 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-09T07:47:49-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4ec58edf-1181-4975-bae3-d1d3a7de4e44'	System	09 Mar 2021 12:47:56
User entered 'No (N)'	System	09 Mar 2021 12:47:56

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-09T07:47:52-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4ec58edf-1181-4975-bae3-d1d3a7de4e44'	System	09 Mar 2021 12:47:56
User entered 'No (N)'	System	09 Mar 2021 12:47:56

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-09T07:47:54-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '4ec58edf-1181-4975-bae3-d1d3a7de4e44' User entered '09 Mar 2021 07:47:54'	System	09 Mar 2021 12:47:56
	System	09 Mar 2021 12:47:56

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Mar 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Mar 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-17T12:47:04-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '024104e9-2c58-4304-9b8d-d01095f1c03a'	System	17 Mar 2021 16:47:12
User entered 'No (N)'	System	17 Mar 2021 16:47:12

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-17T12:47:06-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '024104e9-2c58-4304-9b8d-d01095f1c03a'	System	17 Mar 2021 16:47:12
User entered 'No (N)'	System	17 Mar 2021 16:47:12

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-17T12:47:09-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '024104e9-2c58-4304-9b8d-d01095f1c03a'	System	17 Mar 2021 16:47:12
User entered '17 Mar 2021 12:47:09'	System	17 Mar 2021 16:47:12

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Mar 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Mar 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-23T15:51:24-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9eee1fe8-8a15-401b-9e3d-f8dea1b07334'	System	23 Mar 2021 19:51:35
User entered 'No (N)'	System	23 Mar 2021 19:51:35

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-23T15:51:27-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9eee1fe8-8a15-401b-9e3d-f8dea1b07334'	System	23 Mar 2021 19:51:35
User entered 'No (N)'	System	23 Mar 2021 19:51:35

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-23T15:51:29-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '9eee1fe8-8a15-401b-9e3d-f8dea1b07334'	System	23 Mar 2021 19:51:35
User entered '23 Mar 2021 15:51:29'	System	23 Mar 2021 19:51:35

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Mar 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Mar 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-31T12:32:48-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '37da50c5-b620-469b-badc-f620b3d61474' User entered 'No (N)'	System	31 Mar 2021 16:32:57
	System	31 Mar 2021 16:32:57

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-31T12:32:49-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '37da50c5-b620-469b-badc-f620b3d61474'	System	31 Mar 2021 16:32:57
User entered 'No (N)'	System	31 Mar 2021 16:32:57

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-31T12:32:51-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '37da50c5-b620-469b-badc-f620b3d61474' User entered '31 Mar 2021 12:32:51'	System	31 Mar 2021 16:32:57
	System	31 Mar 2021 16:32:57

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Mar 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '03 Apr 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-06T16:55:41-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f31f0d4d-d883-4741-97a3-a92c719f1dc0'	System	06 Apr 2021 20:55:48
User entered 'No (N)'	System	06 Apr 2021 20:55:48

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-06T16:55:43-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f31f0d4d-d883-4741-97a3-a92c719f1dc0'	System	06 Apr 2021 20:55:48
User entered 'No (N)'	System	06 Apr 2021 20:55:48

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-06T16:55:45-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'f31f0d4d-d883-4741-97a3-a92c719f1dc0'	System	06 Apr 2021 20:55:48
User entered '06 Apr 2021 16:55:45'	System	06 Apr 2021 20:55:48

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Apr 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '10 Apr 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-13T08:09:22-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '429be590-5798-43f1-a9b2-db0149947d25'	System	13 Apr 2021 12:09:28
User entered 'No (N)'	System	13 Apr 2021 12:09:28

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-13T08:09:24-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '429be590-5798-43f1-a9b2-db0149947d25'	System	13 Apr 2021 12:09:28
User entered 'No (N)'	System	13 Apr 2021 12:09:28

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-13T08:09:26-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '429be590-5798-43f1-a9b2-db0149947d25'	System	13 Apr 2021 12:09:28
User entered '13 Apr 2021 08:09:26'	System	13 Apr 2021 12:09:28

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Apr 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '17 Apr 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-23T14:10:36-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3167ae9-dbc1-4f46-aeel-b2d722bee330'	System	23 Apr 2021 18:10:47
User entered 'No (N)'	System	23 Apr 2021 18:10:47

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-23T14:10:38-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3167ae9-dbc1-4f46-aeel-b2d722bee330'	System	23 Apr 2021 18:10:47
User entered 'No (N)'	System	23 Apr 2021 18:10:47

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-23T14:10:42-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: 'e3167ae9-dbc1-4f46-ae1-b2d722bee330'	System	23 Apr 2021 18:10:47
User entered '23 Apr 2021 14:10:42'	System	23 Apr 2021 18:10:47

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Apr 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '24 Apr 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-27T07:56:04-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '24420fb4-90ed-4179-be13-9ae3921e3277'	System	27 Apr 2021 19:10:12
User entered 'No (N)'	System	27 Apr 2021 19:10:12

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-27T07:56:06-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '24420fb4-90ed-4179-be13-9ae3921e3277'	System	27 Apr 2021 19:10:12
User entered 'No (N)'	System	27 Apr 2021 19:10:12

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-04-27T07:56:08-04:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '24420fb4-90ed-4179-be13-9ae3921e3277'	System	27 Apr 2021 19:10:12
User entered '27 Apr 2021 07:56:08'	System	27 Apr 2021 19:10:12

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Apr 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 May 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '04 May 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 May 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '11 May 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '15 May 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '18 May 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '22 May 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '25 May 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '29 May 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 Jun 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Jun 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 Jun 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Jun 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '15 Jun 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Jun 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '22 Jun 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Jun 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '29 Jun 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '03 Jul 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Jul 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '10 Jul 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Jul 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '17 Jul 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Jul 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '24 Jul 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Jul 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '31 Jul 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '03 Aug 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '07 Aug 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '10 Aug 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '14 Aug 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '17 Aug 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '21 Aug 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '24 Aug 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '28 Aug 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '31 Aug 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '04 Sep 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '07 Sep 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '11 Sep 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '14 Sep 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '18 Sep 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '21 Sep 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '25 Sep 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '28 Sep 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Oct 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Oct 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Oct 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Oct 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Oct 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Oct 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Oct 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Oct 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Oct 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Nov 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Nov 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Nov 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Nov 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Nov 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Nov 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Nov 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Nov 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Nov 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '04 Dec 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '07 Dec 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '11 Dec 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '14 Dec 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '18 Dec 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '21 Dec 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '25 Dec 2021 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '28 Dec 2021 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 Jan 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '04 Jan 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 Jan 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '11 Jan 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '15 Jan 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '18 Jan 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '22 Jan 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '25 Jan 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '29 Jan 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 Feb 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Feb 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 Feb 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Feb 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '15 Feb 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Feb 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '22 Feb 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Feb 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 Mar 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Mar 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 Mar 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Mar 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '15 Mar 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Mar 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '22 Mar 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Mar 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '29 Mar 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Apr 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Apr 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Apr 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Apr 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Apr 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Apr 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Apr 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Apr 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Apr 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '03 May 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '07 May 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '10 May 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '14 May 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '17 May 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '21 May 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '24 May 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '28 May 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '31 May 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '04 Jun 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '07 Jun 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '11 Jun 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '14 Jun 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '18 Jun 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '21 Jun 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '25 Jun 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '28 Jun 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Jul 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '05 Jul 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Jul 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '12 Jul 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Jul 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '19 Jul 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Jul 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '26 Jul 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Jul 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '02 Aug 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Aug 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '09 Aug 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Aug 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '16 Aug 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Aug 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '23 Aug 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Aug 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '30 Aug 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '03 Sep 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '06 Sep 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '10 Sep 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '13 Sep 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '17 Sep 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '20 Sep 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '24 Sep 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '27 Sep 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '01 Oct 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '04 Oct 2022 00:01'	System	19 Nov 2020 11:29:31

US3722025

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:25:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:29:31
Amendment Manager: User entered '08 Oct 2022 23:59'	System	19 Nov 2020 11:29:31

US3722025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:25:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:01:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-03T12:28:36-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '59b4356a-d28b-4ffb-ab3f-9ea02d1c25a3'	System	09 Mar 2021 12:47:55
User entered 'Yes (Y)'	System	09 Mar 2021 12:47:55

US3722025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:25:29

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:01:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-03T12:28:42-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '59b4356a-d28b-4ffb-ab3f-9ea02d1c25a3'	System	09 Mar 2021 12:47:55
User entered 'No (N)'	System	09 Mar 2021 12:47:55

US3722025

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:25:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 15:01:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4D1FEAC-D37C-4645-BE47-CE61BA06ED6E)', Time: '2021-03-03T12:28:44-05:00', User OID: 'PatientReportedOutcome (US3722025)', ODM File OID: '59b4356a-d28b-4ffb-ab3f-9ea02d1c25a3' User entered '03 Mar 2021 12:28:44'	System	09 Mar 2021 12:47:55
	System	09 Mar 2021 12:47:55

US3722025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:14
User entered 'Yes (Y)'	Marlee Smith (b) (4)	22 Oct 2020 12:15:26

US3722025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:14
User entered '22 Oct 2020'	Marlee Smith (b) (4)	22 Oct 2020 12:15:26

US3722025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:14
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	22 Oct 2020 12:15:26

US3722025

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:14
User entered empty.	Marlee Smith (b) (4)	22 Oct 2020 12:15:26

US3722025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User signature succeeded.	Luis De La Cruz (b) (4)	25 Feb 2021 17:12:14
User entered 'Yes (Y)'	Marlee Smith (b) (4)	22 Oct 2020 12:15:29

US3722025

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 15:43:10
User entered 'I'	System	22 Oct 2020 12:15:29

US3722025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	30 Nov 2020 18:35:03

US3722025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '25 Nov 2020'	Marlee Smith (b) (4)	30 Nov 2020 18:35:03

US3722025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Contact Made (CONTACT MADE)'	Marlee Smith (b) (4)	30 Nov 2020 18:35:03

US3722025

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered empty.	Marlee Smith (b) (4)	30 Nov 2020 18:35:03

US3722025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:08
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	30 Nov 2020 18:35:05

US3722025

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:00:08
User entered '1'	System	30 Nov 2020 18:35:05

US3722025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	28 Dec 2020 16:23:24

US3722025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '28 Dec 2020'	Taylor Wilson (b) (4)	28 Dec 2020 16:23:24

US3722025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	28 Dec 2020 16:23:24

US3722025

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered empty.	Taylor Wilson (b) (4)	28 Dec 2020 16:23:24

US3722025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:14
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	28 Dec 2020 16:23:33

US3722025

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:15:14
User entered 'I'	System	28 Dec 2020 16:23:33

US3722025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	28 Jan 2021 15:19:32

US3722025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '28 Jan 2021'	Taylor Wilson (b) (4)	28 Jan 2021 15:19:32

US3722025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Contact Not Made (CONTACT NOT MADE)'	Taylor Wilson (b) (4)	28 Jan 2021 15:19:32

US3722025

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Several attempts have been made to contact subject for site call visit but have not been successful with reaching patient or received a call back. Visit has now been closed.'	Taylor Wilson (b) (4)	28 Jan 2021 15:19:32

US3722025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:30
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	28 Jan 2021 15:19:38

US3722025

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:00:30
User entered 'I'	System	28 Jan 2021 15:19:38

US3722025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Feb 2021 13:48:08
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered '10 Feb 2021'	Marlee Smith (b) (4)	10 Feb 2021 13:48:08
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	10 Feb 2021 13:48:08
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered 'VISIT4'	System	10 Feb 2021 13:48:08

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '10 Feb 2021'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '08:21'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered '10 Feb 2021 08:21'	System	29 Mar 2021 15:58:48

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '98.4' F	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Oral (Oral)'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '69'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered 'bpm'	System	29 Mar 2021 15:58:48

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '14'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered 'breaths/min'	System	29 Mar 2021 15:58:48

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '99'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered 'mmHg'	System	29 Mar 2021 15:58:48

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '69'	Marlee Smith (b) (4)	29 Mar 2021 15:58:48
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered 'mmHg'	System	29 Mar 2021 15:58:48

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37

US3722025

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:25:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37

US3722025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered 'No (N)'	Marlee Smith (b) (4)	10 Feb 2021 13:48:13
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:25:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered empty.	Marlee Smith (b) (4)	10 Feb 2021 13:48:13
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	02 Mar 2021 19:27:06
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered '10 Feb 2021'	Marlee Smith (b) (4)	02 Mar 2021 19:27:06
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered '08:29'	Marlee Smith (b) (4)	02 Mar 2021 19:27:06
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered '10 Feb 2021 08:29'	System	02 Mar 2021 19:27:06

US3722025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User signature succeeded.	Luis De La Cruz (b) (4)	09 Mar 2021 11:13:29
	(b) (4)	
User entered 'Yes (Y)'	Marlee Smith (b) (4)	10 Feb 2021 13:48:17
	(b) (4)	

US3722025

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:42:37
User entered '1'	System	10 Feb 2021 13:48:17

US3722025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	23 Mar 2021 13:31:50

US3722025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '23 Mar 2021'	Taylor Wilson (b) (4)	23 Mar 2021 13:31:50

US3722025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	23 Mar 2021 13:31:50

US3722025

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered empty.	Taylor Wilson (b) (4)	23 Mar 2021 13:31:50

US3722025

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:07
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	23 Mar 2021 13:31:56

US3722025

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:51:07
User entered '1'	System	23 Mar 2021 13:31:56

US3722025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Apr 2021 18:24:19
	(b) (4)	

US3722025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User closed query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 04:24:23
Query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Subject was contacted with in window of visit' (Site from System).	Taylor Wilson (b) (4) (b) (4)	01 Apr 2021 18:24:42
User opened query 'Safety Call Day 269 'Date of Contact or Contact Attempt' is less than 237 days or greater than 243 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	01 Apr 2021 18:24:19
User entered '01 Apr 2021'	Taylor Wilson (b) (4) (b) (4)	01 Apr 2021 18:24:19

US3722025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Taylor Wilson (b) (4)	01 Apr 2021 18:24:19
	(b) (4)	

US3722025

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:25:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Taylor Wilson (b) (4)	01 Apr 2021 18:24:19
	(b) (4)	

US3722025

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Yes (Y)'	Taylor Wilson (b) (4)	01 Apr 2021 18:24:48
	(b) (4)	

US3722025

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:25:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 18:24:48

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Jan 2021 22:48:43

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 22:48:43

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Clinic (Clinic)'	Marlee Smith (b) (4)	08 Jan 2021 22:48:43

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:25:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 22:48:43

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '0'	(b) (4) Marlee Smith (b) (4)	22 Apr 2021 12:21:39
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:08:47

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User closed query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:09:46
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 12:21:42
User entered 'Amendment 6 or later (Amendment 6 or later)'	Marlee Smith (b) (4) (b) (4)	22 Apr 2021 12:21:39
User opened query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 05:55:25
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:08:47

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 05:58:21
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	08 Jan 2021 22:48:52
	(b) (4)	

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 05:58:21
User entered 'mRNA-1273 (mRNA-1273)'	Marlee Smith (b) (4)	08 Jan 2021 22:48:52
	(b) (4)	

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'No (N)'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User entered empty.	System	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:25:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User entered empty.	System	08 Jan 2021 22:48:52

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Jan 2021 22:49:01

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '8 Jan 2021'	Marlee Smith (b) (4)	08 Jan 2021 22:49:01

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '16:18'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 22:49:01

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:25:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User entered '8 Jan 2021 16:18'	System	08 Jan 2021 22:49:01

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered 'Yes (Y)'	Marlee Smith (b) (4)	08 Jan 2021 22:49:09

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '8 Jan 2021'	(b) (4) Marlee Smith (b) (4)	08 Jan 2021 22:49:09

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User entered '16:19'	(b) (4) Marlee Smith (b) (4) (b) (4)	08 Jan 2021 22:49:09

US3722025

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:25:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:15:53
User entered '8 Jan 2021 16:19'	System	08 Jan 2021 22:49:09

US3722025

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:25:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:46:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User closed query 'Per sponsor review: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:00:47
Query 'Per sponsor review: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' answered with 'Completed and updated per request' (Site from DM).	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:34:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:06
User opened query 'Per sponsor review: Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary, Fatigue lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 23:56:11
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:54:35

US3722025

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:25:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'Per instruction we were told to delete all the AE's as they stated that they did not qualify as AE. So the answer to the summery is not No. Resolved. ' (Site from DM).	Sara Poff (b) (4)	16 Feb 2021 18:39:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	16 Feb 2021 18:38:27
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 1; end date: Day 9). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:09:14
User entered 'Yes (Y)'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:40:48

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[AEID](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 17:49:36

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User closed query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if meets AE reporting criteria. Please review if recorded event meets criteria, otherwise delete if applicable. Update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 03:49:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 12:34:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 12:34:31
Data point term sent to Coder	System	19 Apr 2021 12:33:42
Query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if meets AE reporting criteria. Please review if recorded event meets criteria, otherwise delete if applicable. Update as appropriate, otherwise provide clarification.' answered with 'Meets criteria ' (Site from DM).	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:33:38
DataPoint activated with code reason code Data required.	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:51
Data point term sent to Coder	System	21 Sep 2020 17:49:40
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 17:49:36
User opened query 'Per DM CLR: Please note that solicited reactions are only to be reported as AE if meets AE reporting criteria. Please review if recorded event meets criteria, otherwise delete if applicable. Update as appropriate, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:07:11
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 00:48:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Aug 2020 00:48:32
Data point term sent to Coder	System	10 Aug 2020 00:47:30
User entered 'FATIGUE'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:47:16

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'No (N)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
DataPoint activated with code reason code Data required.	(b) (4) Sara Poff (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	(b) (4) Amy Ford (b) (4)	21 Sep 2020 17:49:36
User closed query 'Per CDM: Form recently updated. Please provide a Yes or No response to "Is this event a confirmed diagnosis of Symptomatic Covid-19"?' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 17:39:25
Query 'Per CDM: Form recently updated. Please provide a Yes or No response to "Is this event a confirmed diagnosis of Symptomatic Covid-19"?' answered with 'Response updated.' (Site from DM).	Amy Ford (b) (4) (b) (4)	18 Sep 2020 12:51:27
User entered 'No (N)'	Amy Ford (b) (4) (b) (4)	18 Sep 2020 12:51:12
User opened query 'Per CDM: Form recently updated. Please provide a Yes or No response to "Is this event a confirmed diagnosis of Symptomatic Covid-19"?' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 13:48:02
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:39:40

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
Query 'Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly. ' canceled (Site from DM).	(b) (4)	
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	Amy Ford (b) (4)	21 Sep 2020 17:49:36
User opened query 'Per CDM: Date format is not correctly recorded. Please review the day field it must be 2 digits (XX). Leading zeros are acceptable, if applicable. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 12:30:51
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 14:58:42
User entered '2 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 13:48:22
	System	28 Aug 2020 20:26:29
	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '13:00'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 17:49:36
User entered '2 Aug 2020 13:00'	System	10 Aug 2020 00:47:16

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'No (N)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '10 Aug 2020' reason for change: Data Entry Error	Sara Poff (b) (4)	19 Apr 2021 12:33:22
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '7 Aug 2020'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '20:00'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '10 Aug 2020 20:00'	System	19 Apr 2021 12:33:22
DataPoint activated with code reason code Data required.	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 17:49:36
User entered '7 Aug 2020 20:00'	System	10 Aug 2020 00:47:16

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'No (N)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'Related (RELATED)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'None (NONE)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

None

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'I'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:47:16
	(b) (4)	

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 17:49:36
Amendment Manager: User entered '0'	System	21 Aug 2020 01:39:43
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:39:40

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sara Poff (b) (4) (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4) (b) (4)	21 Sep 2020 17:49:36
Amendment Manager: User entered '0'	System	21 Aug 2020 01:39:43
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:39:40

US3722025

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 12 Aug 2021 13:25:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Sara Poff (b) (4)	19 Apr 2021 12:32:51
DataPoint inactivated with code reason code Data not required.	Amy Ford (b) (4)	21 Sep 2020 17:49:36
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:39:40

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:25:29

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:46:26
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 18:34:34
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'This has been entered and completed ' (Site from DM).	Sara Poff (b) (4) (b) (4)	01 Apr 2021 14:21:45
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:54:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:39:03
User entered 'No (N)'	Kayla Peay (b) (4) (b) (4)	05 Aug 2020 20:12:48

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 17:48:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:48:33
Data point term sent to Coder	System	18 Sep 2020 17:47:29
User closed query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	18 Sep 2020 17:47:15
Query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'Medication was ibuprofen, but inadvertently typed profen.' (Site from System).	Amy Ford (b) (4) (b) (4)	18 Sep 2020 17:47:15
User entered 'ibuPROFEN' reason for change: Data Entry Error	Amy Ford (b) (4) (b) (4)	18 Sep 2020 17:46:40
User opened query 'DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4) (b) (4)	08 Sep 2020 08:26:38
Data point term sent to Coder	System	10 Aug 2020 00:40:28
User entered 'PROFEN'	Amy Ford (b) (4) (b) (4)	10 Aug 2020 00:40:21

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'No (N)'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'HEADACHE'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '200'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'mg (mg)'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'as needed (PRN)'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Oral (ORAL)'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '3 Aug 2020'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '0'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Yes (Y)'	Amy Ford (b) (4)	10 Aug 2020 00:40:21
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 00:40:21

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 00:40:21

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:25:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 00:40:21

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL; FERROUS FUMARATE; NORETHISTERONE ACETATE, PRODUCTSYNONYM: LOESTRIN FE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Aug 2020 10:05:20
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 10:05:20
Data point term sent to Coder	System	12 Aug 2020 19:26:00
Data point term sent to Coder	System	10 Aug 2020 19:10:15
User entered 'loestrin FE'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:09:50

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Birth control' reason for change: Data Entry Error	Kayla Peay (b) (4)	12 Aug 2020 19:25:49
	(b) (4)	
User entered 'medical history'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '1/20'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'mg (mg)'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'once daily (QD)'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Oral (ORAL)'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 13:23:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'to be recorded per protocol' (Site from System).	Amy Ford (b) (4) (b) (4)	11 Aug 2020 01:29:57
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 19:09:50
User entered 'un UNK 2007'	Kayla Peay (b) (4) (b) (4)	10 Aug 2020 19:09:50

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered '0'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'Yes (Y)'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered empty.	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	10 Aug 2020 19:09:50
	(b) (4)	

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 19:09:50

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 19:09:50

US3722025

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:25:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 19:09:50

US3722025

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:25:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Luis De La Cruz (b) (4)	28 Apr 2021 21:47:41
	(b) (4)	
User entered 'No (N)'	Kayla Peay (b) (4)	05 Aug 2020 20:13:07
	(b) (4)	